HOSPITAL MEDICINES LIST
RESTRICTIONS CHECKLISTS
July 2025

Therapeutic Groups

Alimentary Tract and Metabolism

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Calcium carbonate

INITIATION

Prerequisites (tick box where appropriate)

○ Only when prescribed for patients unable to swallow calcium carbonate tablets or where calcium carbonate tablets are inappropriate.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Budesonide

INITIATION – Crohn's disease

Prerequisites (tick boxes where appropriate)

- ○ Mild to moderate ileal, ileocaecal or proximal Crohn's disease

and

- ○ Diabetes

or

- ○ Cushingoid habitus

or

- ○ Osteoporosis where there is significant risk of fracture

or

- ○ Severe acne following treatment with conventional corticosteroid therapy

or

- ○ History of severe psychiatric problems associated with corticosteroid treatment

or

- ○ History of major mental illness (such as bipolar affective disorder) where the risk of conventional corticosteroid treatment causing relapse is considered to be high

or

- ○ Relapse during pregnancy (where conventional corticosteroids are considered to be contraindicated)

INITIATION – Collagenous and lymphocytic colitis (microscopic colitis)

Prerequisites (tick box where appropriate)

- ○ Patient has a diagnosis of microscopic colitis (collagenous or lymphocytic colitis) by colonoscopy with biopsies

INITIATION – Gut Graft versus Host disease

Prerequisites (tick box where appropriate)

- ○ Patient has gut Graft versus Host disease following allogenic bone marrow transplantation

I confirm that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Budesonide *- continued*

INITIATION – non-cirrhotic autoimmune hepatitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has autoimmune hepatitis*

and

- ○ Patient does not have cirrhosis

and

- ○ Diabetes

or

- ○ Cushingoid habitus

or

- ○ Osteoporosis where there is significant risk of fracture

or

- ○ Severe acne following treatment with conventional corticosteroid therapy

or

- ○ History of severe psychiatric problems associated with corticosteroid treatment

or

- ○ History of major mental illness (such as bipolar affective disorder) where the risk of conventional corticosteroid treatment causing relapse is considered to be high

or

- ○ Relapse during pregnancy (where conventional corticosteroids are considered to be contraindicated)

or

- ○ Adolescents with poor linear growth (where conventional corticosteroid use may limit further growth)

Note: Indications marked with * are unapproved indications.

CONTINUATION – non-cirrhotic autoimmune hepatitis
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ Treatment remains appropriate and the patient is benefitting from the treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ranitidine

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For continuation use

or

- ○ Routine prevention of allergic reactions.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Omeprazole - Tab dispersible 10 mg and 20 mg

INITIATION

Prerequisites (tick box where appropriate)

○ Only for use in tube-fed patients

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

L-ornithine L-aspartate

INITIATION

Prerequisites (tick box where appropriate)

- ○ For patients with chronic hepatic encephalopathy who have not responded to treatment with, or are intolerant to lactulose, or where lactulose is contraindicated

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rifaximin

INITIATION

Prerequisites (tick box where appropriate)

- ○ For patients with hepatic encephalopathy despite an adequate trial of maximum tolerated doses of lactulose

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Diazoxide

INITIATION

Prerequisites (tick box where appropriate)

- ○ For patients with confirmed hypoglycaemia caused by hyperinsulinism

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Dulaglutide

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For continuation use

or

- ○ Patient has type 2 diabetes

and

- ○ Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of all of the following funded blood glucose lowering agents for a period of least 6 months, where clinically appropriate: empagliflozin, metformin, and vildagliptin

and

- ○ Patient is Māori or any Pacific ethnicity*

or

- ○ Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*

or

- ○ Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*

or

- ○ Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*

or

- ○ Patient has diabetic kidney disease (see note b)*

Note: * Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.

a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.

b) Diabetic kidney disease defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause identified.

c) Funded GLP-1a treatment is not to be given in combination with (empagliflozin / empagliflozin with metformin hydrochloride) unless receiving (empagliflozin or empagliflozin in combination with metformin hydrochloride) for the treatment of heart failure.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Liraglutide

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For continuation use

or

- ○ Patient has type 2 diabetes

and

- ○ Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of all of the following funded blood glucose lowering agents for a period of least 6 months, where clinically appropriate: empagliflozin, metformin, and vildagliptin

and

- ○ Patient is Māori or any Pacific ethnicity*

or

- ○ Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*

or

- ○ Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*

or

- ○ Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*

or

- ○ Patient has diabetic kidney disease (see note b)*

Note: * Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.

a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.

b) Diabetic kidney disease defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause identified.

c) Funded GLP-1a treatment is not to be given in combination with (empagliflozin / empagliflozin with metformin hydrochloride) unless receiving (empagliflozin or empagliflozin in combination with metformin hydrochloride) for the treatment of heart failure.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Empagliflozin; Empagliflozin with metformin hydrochloride

INITIATION – heart failure reduced ejection fraction

Prerequisites (tick boxes where appropriate)

- ○ Patient has heart failure

and

- ○ Patient is in NYHA functional class II or III or IV

and

- ○ Patient has a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%

or

- ○ An ECHO is not reasonably practicable, and in the opinion of the treating practitioner the patient would benefit from treatment

and

- ○ Patient is receiving concomitant optimal standard funded chronic heart failure treatment

INITIATION – Type 2 Diabetes

Prerequisites (tick boxes where appropriate)

- ○ For continuation use

or

- ○ Patient has previously had an initial approval for a GLP-1 agonist

or

- ○ Patient has type 2 diabetes

and

- ○ Patient is Māori or any Pacific ethnicity*

or

- ○ Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*

or

- ○ Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*

or

- ○ Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*

or

- ○ Patient has diabetic kidney disease (see note b)*

and

- ○ Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood-glucose lowering agent (e.g. metformin, vildagliptin, or insulin) for at least 3 months

Note: * Criteria intended to describe patients at high risk of cardiovascular or renal complications of diabetes.

a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.

b) Diabetic kidney disease defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause.

c) Funded [empagliflozin / empagliflozin with metformin hydrochloride] treatment is not to be given in combination with a funded GLP-1 unless receiving (empagliflozin / empagliflozin with metformin hydrochloride] for the treatment of heart failure.

I confirm that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ursodeoxycholic acid

INITIATION – Alagille syndrome or progressive familial intrahepatic cholestasis
Prerequisites (tick boxes where appropriate)

- ○ Patient has been diagnosed with Alagille syndrome

or

- ○ Patient has progressive familial intrahepatic cholestasis

INITIATION – Chronic severe drug induced cholestatic liver injury
Prerequisites (tick boxes where appropriate)

- ○ Patient has chronic severe drug induced cholestatic liver injury

and

- ○ Cholestatic liver injury not due to Total Parenteral Nutrition (TPN) use in adults

and

- ○ Treatment with ursodeoxycholic acid may prevent hospital admission or reduce duration of stay

INITIATION – Primary biliary cholangitis
Prerequisites (tick boxes where appropriate)

- ○ Primary biliary cholangitis confirmed by antimitochondrial antibody titre (AMA) > 1:80, and raised cholestatic liver enzymes with or without raised serum IgM or, if AMA is negative by liver biopsy

and

- ○ Patient not requiring a liver transplant (bilirubin > 100 umol/l; decompensated cirrhosis

INITIATION – Pregnancy
Prerequisites (tick box where appropriate)

- ○ Patient diagnosed with cholestasis of pregnancy

INITIATION – Haematological transplant
Prerequisites (tick boxes where appropriate)

- ○ Patient at risk of veno-occlusive disease or has hepatic impairment and is undergoing conditioning treatment prior to allogenic stem cell or bone marrow transplantation

and

- ○ Treatment for up to 13 weeks

INITIATION – Total parenteral nutrition induced cholestasis
Prerequisites (tick boxes where appropriate)

- ○ Paediatric patient has developed abnormal liver function as indicated on testing which is likely to be induced by TPN

and

- ○ Liver function has not improved with modifying the TPN composition

INITIATION – prevention of sinusoidal obstruction syndrome
Prerequisites (tick box where appropriate)

- ○ The individual has leukaemia/lymphoma and requires prophylaxis for medications/therapies with a high risk of sinusoidal obstruction syndrome

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Methylnaltrexone bromide

INITIATION – Opioid induced constipation

Prerequisites (tick boxes where appropriate)

- ○ The patient is receiving palliative care

and

- ○ Oral and rectal treatments for opioid induced constipation are ineffective

or

- ○ Oral and rectal treatments for opioid induced constipation are unable to be tolerated

INITIATION – Opioid induced constipation outside of palliative care

Re-assessment required after 14 days

Prerequisites (tick boxes where appropriate)

- ○ Individual has opioid induced constipation

and

- ○ Oral and rectal treatments for opioid induced constipation, including bowel-cleansing preparations, are ineffective or inappropriate

and

- ○ Mechanical bowel obstruction has been excluded

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

sodium picosulfate

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ The patient is a child with problematic constipation despite an adequate trial of other oral pharmacotherapies including macrogol where practicable

and

- ○ The patient would otherwise require a high-volume bowel cleansing preparation

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Betaine

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a confirmed diagnosis of homocystinuria

and

- ○ A cystathionine beta-synthase (CBS) deficiency

or

- ○ A 5,10-methylene-tetrahydrofolate reductase (MTHFR) deficiency

or

- ○ A disorder of intracellular cobalamin metabolism

and

- ○ An appropriate homocysteine level has not been achieved despite a sufficient trial of appropriate vitamin supplementation

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The treatment remains appropriate and the patient is benefiting from treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Levocarnitine

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a neurologist, metabolic physician or metabolic disorders dietitian, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sodium phenylbutyrate

INITIATION
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ For the chronic management of a urea cycle disorder involving a deficiency of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The treatment remains appropriate and the patient is benefiting from treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Biotin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician or metabolic disorders dietitian, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pyridoxal-5-phosphate

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a neurologist, metabolic physician or metabolic disorders dietitian, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Galsulfase

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has been diagnosed with mucopolysaccharidosis VI

and

- ○ Diagnosis confirmed by demonstration of N-acetyl-galactosamine-4-sulfatase (arylsulfatase B) deficiency confirmed by either enzyme activity assay in leukocytes or skin fibroblasts

or

- ○ Detection of two disease causing mutations and patient has a sibling who is known to have mucopolysaccharidosis VI

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The treatment remains appropriate for the patient and the patient is benefiting from treatment

and

- ○ Patient has not had severe infusion-related adverse reactions which were not preventable by appropriate pre-medication and/or adjustment of infusion rates

and

- ○ Patient has not developed another life threatening or severe disease where the long term prognosis is unlikely to be influenced by Enzyme Replacement Therapy (ERT)

and

- ○ Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Alglucosidase Alfa

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient is aged up to 24 months at the time of initial application and has been diagnosed with infantile Pompe disease

and

- ○ Diagnosis confirmed by documented deficiency of acid alpha-glucosidase by prenatal diagnosis using chorionic villus biopsies and/or cultured amniotic cells

or

- ○ Documented deficiency of acid alpha-glucosidase, and urinary tetrasaccharide testing indicating a diagnostic elevation of glucose tetrasaccharides

or

- ○ Documented deficiency of acid alpha-glucosidase, and documented molecular genetic testing indicating a disease-causing mutation in the acid alpha-glucosidase gene (GAA gene)

or

- ○ Documented urinary tetrasaccharide testing indicating a diagnostic elevation of glucose tetrasaccharides, and molecular genetic testing indicating a disease-causing mutation in the GAA gene

and

- ○ Patient has not required long-term invasive ventilation for respiratory failure prior to starting enzyme replacement therapy (ERT)

and

- ○ Patient does not have another life-threatening or severe disease where the prognosis is unlikely to be influenced by ERT or might be reasonably expected to compromise a response to ERT

and

- ○ Alglucosidase alfa to be administered at doses no greater than 20 mg/kg every 2 weeks

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The treatment remains appropriate for the patient and the patient is benefiting from treatment

and

- ○ Alglucosidase alfa to be administered at doses no greater than 20 mg/kg every 2 weeks

and

- ○ Patient has not had severe infusion-related adverse reactions which were not preventable by appropriate pre-medication and/or adjustment of infusion rates

and

- ○ Patient has not developed another life threatening or severe disease where the long term prognosis is unlikely to be influenced by ERT

and

- ○ Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT

and

- ○ There is no evidence of life threatening progression of respiratory disease as evidenced by the needed for > 14 days of invasive ventilation

and

- ○ There is no evidence of new or progressive cardiomyopathy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Idursulfase

INITIATION
Re-assessment required after 24 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has been diagnosed with Hunter Syndrome (mucopolysacchardosis II)

and

- ○ Diagnosis confirmed by demonstration of iduronate 2-sulfatase deficiency in white blood cells by either enzyme assay in cultured skin fibroblasts

or

- ○ Detection of a disease causing mutation in the iduronate 2-sulfatase gene

and

- ○ Patient is going to proceed with a haematopoietic stem cell transplant (HSCT) within the next 3 months and treatment with idursulfase would be bridging treatment to transplant

and

- ○ Patient has not required long-term invasive ventilation for respiratory failure prior to starting Enzyme Replacement Therapy (ERT)

and

- ○ Idursulfase to be administered for a total of 24 weeks (equivalent to 12 weeks pre- and 12 weeks post-HSCT) at doses no greater than 0.5 mg/kg every week

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Laronidase

INITIATION
Re-assessment required after 24 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has been diagnosed with Hurler Syndrome (mucopolysacchardosis I-H)

and

- ○ Diagnosis confirmed by demonstration of alpha-L-iduronidase deficiency in white blood cells by either enzyme assay in cultured skin fibroblasts

or

- ○ Detection of two disease causing mutations in the alpha-L-iduronidase gene and patient has a sibling who is known to have Hurler syndrome

and

- ○ Patient is going to proceed with a haematopoietic stem cell transplant (HSCT) within the next 3 months and treatment with laronidase would be bridging treatment to transplant

and

- ○ Patient has not required long-term invasive ventilation for respiratory failure prior to starting Enzyme Replacement Therapy (ERT)

and

- ○ Laronidase to be administered for a total of 24 weeks (equivalent to 12 weeks pre- and 12 post-HSCT) at doses no greater than 100 units/kg every week

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Taliglucerase alfa

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a diagnosis of symptomatic type 1 or type 3* Gaucher disease confirmed by the demonstration of specific deficiency of glucocerebrosidase in leukocytes or cultured skin fibroblasts, and genotypic analysis

and

- ○ Patient does not have another life-threatening or severe disease where the prognosis is unlikely to be influenced by enzyme replacement therapy (ERT) or the disease might be reasonably expected to compromise a response to ERT

and

- ○ Patient has haematological complications of Gaucher disease

or

- ○ Patient has skeletal complications of Gaucher disease

or

- ○ Patient has significant liver dysfunction or hepatomegaly attributable to Gaucher disease

or

- ○ Patient has reduced vital capacity from clinically significant or progressive pulmonary disease due to Gaucher disease

or

- ○ Patient is a child and has experienced growth failure with significant decrease in percentile linear growth over a 6-12 month period

and

- ○ Taliglucerase alfa is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest whole vial (200 units)

Note: Indication marked with * is an unapproved indication

CONTINUATION
Re-assessment required after 3 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician or any relevant practitioner on the recommendation of a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has demonstrated a symptomatic improvement and has maintained improvements in the main symptom or symptoms for which therapy was started

and

- ○ Patient has demonstrated a clinically objective improvement or no deterioration in haemoglobin levels, platelet counts and liver and spleen size

and

- ○ RRadiological (MRI) signs of bone activity performed at two years since initiation of treatment, and five yearly thereafter, demonstrate no deterioration shown by the MRI, compared with MRI taken immediately prior to commencement of therapy or adjusted dose

and

- ○ Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT

and

- ○ Patient is adherent with regular treatment and taliglucerase alfa is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest whole vial (200 units)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sapropterin dihydrochloride

INITIATION
Re-assessment required after 1 month
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has phenylketonuria (PKU) and is pregnant or actively planning to become pregnant

and

- ○ Treatment with sapropterin is required to support management of PKU during pregnancy

and

- ○ Sapropterin to be administered at doses no greater than a total daily dose of 20 mg/kg

and

- ○ Sapropterin to be used alone or in combination with PKU dietary management

and

- ○ Total treatment duration with sapropterin will not exceed 22 months for each pregnancy (includes time for planning and becoming pregnant) and treatment will be stopped after delivery

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Following the initial one-month approval, the patient has demonstrated an adequate response to a 2 to 4 week trial of sapropterin with a clinically appropriate reduction in phenylalanine levels to support management of PKU during pregnancy

or

- ○ On subsequent renewal applications, the patient has previously demonstrated response to treatment with sapropterin and maintained adequate phenylalanine levels to support management of PKU during pregnancy

and

- ○ Patient continues to be pregnant and treatment with sapropterin will not continue after delivery

or

- ○ Patient is actively planning a pregnancy and this is the first renewal for treatment with sapropterin

or

- ○ Treatment with sapropterin is required for a second or subsequent pregnancy to support management of their PKU during pregnancy

and

- ○ Sapropterin to be administered at doses no greater than a total daily dose of 20 mg/kg

and

- ○ Sapropterin to be used alone or in combination with PKU dietary management

and

- ○ Total treatment duration with sapropterin will not exceed 22 months for each pregnancy (includes time for planning and becoming pregnant) and treatment will be stopped after delivery

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Carglumic Acid

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ For the acute in-patient treatment of organic acidaemias as an alternative to haemofiltration

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Coenzyme Q10

INITIATION
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a suspected inborn error of metabolism that may respond to coenzyme Q10 supplementation

CONTINUATION
Re-assessment required after 24 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a confirmed diagnosis of an inborn error of metabolism that responds to coenzyme Q10 supplementation

and

- ○ The treatment remains appropriate and the patient is benefiting from treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Riboflavin

INITIATION
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician or neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a suspected inborn error of metabolism that may respond to riboflavin supplementation

CONTINUATION
Re-assessment required after 24 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician or neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a confirmed diagnosis of an inborn error of metabolism that responds to riboflavin supplementation

and

- ○ The treatment remains appropriate and the patient is benefiting from treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Taurine

INITIATION
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a suspected specific mitochondrial disorder that may respond to taurine supplementation

CONTINUATION
Re-assessment required after 24 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a confirmed diagnosis of a specific mitochondrial disorder which responds to taurine supplementation

and

- ○ The treatment remains appropriate and the patient is benefiting from treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Trientine

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient has confirmed Wilson disease

and

- ○ Treatment with D-penicillamine has been trialled and discontinued because the person has experienced intolerable side effects or has not received sufficient benefit

and

- ○ Treatment with zinc has been trialled and discontinued because the person has experienced intolerable side effects or has not received sufficient benefit, or zinc is considered clinically inappropriate as the person has symptomatic liver disease and requires copper chelation

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Copper chloride

INITIATION – Moderate to severe burns
Re-assessment required after 3 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has been hospitalised with moderate to severe burns

and

- ○ Treatment is recommended by a National Burns Unit specialist

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ferric carboxymaltose

INITIATION

Prerequisites (tick box where appropriate)

- ○ Treatment with oral iron has proven ineffective or is clinically inappropriate

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Selenium

INITIATION – Moderate to severe burns
Re-assessment required after 3 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has been hospitalised with moderate to severe burns

and

- ○ Treatment is recommended by a National Burns Unit specialist

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sodium hyaluronate

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by an otolaryngologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Multivitamins - Cap

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient has cystic fibrosis with pancreatic insufficiency

or

- ○ Patient is an infant or child with liver disease or short gut syndrome

or

- ○ Patient has severe malabsorption syndrome

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Multivitamins – Powder

INITIATION

Prerequisites (tick box where appropriate)

- ○ Patient has inborn errors of metabolism

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Multivitamin and mineral supplement

INITIATION
Re-assessment required after 3 months
Prerequisites (tick boxes where appropriate)

- ❍ Patient was admitted to hospital with burns

and

- ❍ Burn size is greater than 15% of total body surface area (BSA) for all types of burns

or

- ❍ Burn size is greater than 10% of BSA for mid-dermal or deep dermal burns

or

- ❍ Nutritional status prior to admission or dietary intake is poor

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Multivitamin renal

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ The patient has chronic kidney disease and is receiving either peritoneal dialysis or haemodialysis

or

- ○ The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of < 15 ml/min/1.73m^2 body surface area (BSA)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Alpha tocopheryl acetate

INITIATION – Cystic fibrosis

Prerequisites (tick boxes where appropriate)

- ○ Cystic fibrosis patient

and

or

- ○ Patient has tried and failed the other available funded fat soluble vitamin A,D,E,K supplement (Vitabdeck)
- ○ The other available funded fat soluble vitamin A,D,E,K supplement (Vitabdeck) is contraindicated or clinically inappropriate for the patient

INITIATION – Osteoradionecrosis

Prerequisites (tick box where appropriate)

- ○ For the treatment of osteoradionecrosis

INITIATION – Other indications

Prerequisites (tick boxes where appropriate)

- ○ Infant or child with liver disease or short gut syndrome

and

- ○ Requires vitamin supplementation

and

or

- ○ Patient has tried and failed the other available funded fat soluble vitamin A,D,E,K supplements (Vitabdeck)
- ○ The other available funded fat soluble vitamin A,D,E,K supplement (Vitabdeck) is contraindicated or clinically inappropriate for patient

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Alpha tocopheryl

INITIATION – Cystic fibrosis

Prerequisites (tick boxes where appropriate)

- ○ Cystic fibrosis patient

and

or

- ○ Patient has tried and failed the other available funded fat soluble vitamin A,D,E,K supplement (Vitabdeck)
- ○ The other available funded fat soluble vitamin A,D,E,K supplement (Vitabdeck) is contraindicated or clinically inappropriate for the patient

INITIATION – Osteoradionecrosis

Prerequisites (tick box where appropriate)

- ○ For the treatment of osteoradionecrosis

INITIATION – Other indications

Prerequisites (tick boxes where appropriate)

- ○ Infant or child with liver disease or short gut syndrome

and

- ○ Requires vitamin supplementation

and

or

- ○ Patient has tried and failed the other available funded fat soluble vitamin A,D,E,K supplements (Vitabdeck)
- ○ The other available funded fat soluble vitamin A,D,E,K supplement (Vitabdeck) is contraindicated or clinically inappropriate for patient

I confirm that the above details are correct:

Signed: ..... Date: .....

Blood and Blood Forming Organs

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Epoetin beta

INITIATION – chronic renal failure

Prerequisites (tick boxes where appropriate)

- ○ Patient in chronic renal failure

and

- ○ Haemoglobin is less than or equal to 100g/L

and

- ○ Patient does not have diabetes mellitus

  and

  ○ Glomerular filtration rate is less than or equal to 30ml/min

or

- ○ Patient has diabetes mellitus

  and

  ○ Glomerular filtration rate is less than or equal to 45ml/min

or

- ○ Patient is on haemodialysis or peritoneal dialysis

INITIATION – myelodysplasia*

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- ○ Patient has a confirmed diagnosis of myelodysplasia (MDS)

and

- ○ Has had symptomatic anaemia with haemoglobin < 100g/L and is red cell transfusion-dependent

and

- ○ Patient has very low, low or intermediate risk MDS based on the WHO classification-based prognostic scoring system for myelodysplastic syndrome (WPSS)

and

- ○ Other causes of anaemia such as B12 and folate deficiency have been excluded

and

- ○ Patient has a serum epoetin level of < 500 IU/L

and

- ○ The minimum necessary dose of epoetin would be used and will not exceed 80,000 iu per week

CONTINUATION – myelodysplasia*

Re-assessment required after 2 months

Prerequisites (tick boxes where appropriate)

- ○ The patient's transfusion requirement continues to be reduced with epoetin treatment

and

- ○ Transformation to acute myeloid leukaemia has not occurred

and

- ○ The minimum necessary dose of epoetin would be used and will not exceed 80,000 iu per week

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Epoetin beta *- continued*

INITIATION – all other indications

Prerequisites (tick boxes where appropriate)

- ❍ Haematologist

and

- ❍ For use in patients where blood transfusion is not a viable treatment alternative

and

- ❍ *Note: Indications marked with * are unapproved indications

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Epoetin alfa

INITIATION – chronic renal failure

Prerequisites (tick boxes where appropriate)

- ○ Patient in chronic renal failure

and

- ○ Haemoglobin is less than or equal to 100g/L

and

- ○ Patient does not have diabetes mellitus

  and

  ○ Glomerular filtration rate is less than or equal to 30ml/min

or

- ○ Patient has diabetes mellitus

  and

  ○ Glomerular filtration rate is less than or equal to 45ml/min

or

- ○ Patient is on haemodialysis or peritoneal dialysis

INITIATION – myelodysplasia*

Re-assessment required after 2 months

Prerequisites (tick boxes where appropriate)

- ○ Patient has a confirmed diagnosis of myelodysplasia (MDS)

and

- ○ Has had symptomatic anaemia with haemoglobin < 100g/L and is red cell transfusion-dependent

and

- ○ Patient has very low, low or intermediate risk MDS based on the WHO classification-based prognostic scoring system for myelodysplastic syndrome (WPSS)

and

- ○ Other causes of anaemia such as B12 and folate deficiency have been excluded

and

- ○ Patient has a serum epoetin level of < 500 IU/L

and

- ○ The minimum necessary dose of epoetin would be used and will not exceed 80,000 iu per week

CONTINUATION – myelodysplasia*

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- ○ The patient's transfusion requirement continues to be reduced with epoetin treatment

and

- ○ Transformation to acute myeloid leukaemia has not occurred

and

- ○ The minimum necessary dose of epoetin would be used and will not exceed 80,000 iu per week

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Epoetin alfa *- continued*

INITIATION – all other indications

Prerequisites (tick box where appropriate)

- ❍ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ For use in patients where blood transfusion is not a viable treatment alternative

Note: Indications marked with * are unapproved indications

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Aprotinin

INITIATION

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a cardiac anaesthetist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ Paediatric patient undergoing cardiopulmonary bypass procedure

or

❍ Adult patient undergoing cardiac surgical procedure where the significant risk of massive bleeding outweighs the potential adverse effects of the drug

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Eltrombopag

INITIATION – idiopathic thrombocytopenic purpura - post-splenectomy
Re-assessment required after 6 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has had a splenectomy

and

- ○ Two immunosuppressive therapies have been trialled and failed after therapy of 3 months each (or 1 month for rituximab)

and

- ○ Patient has a platelet count of 20,000 to 30,000 platelets per microlitre and has evidence of significant mucocutaneous bleeding

or

- ○ Patient has a platelet count of less than or equal to 20,000 platelets per microlitre and has evidence of active bleeding

or

- ○ Patient has a platelet count of less than or equal to 10,000 platelets per microlitre

INITIATION – idiopathic thrombocytopenic purpura - preparation for splenectomy
Re-assessment required after 6 weeks
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient requires eltrombopag treatment as preparation for splenectomy

CONTINUATION – idiopathic thrombocytopenic purpura - post-splenectomy
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has obtained a response (see Note) from treatment during the initial approval or subsequent renewal periods and further treatment is required

Note: Response to treatment is defined as a platelet count of > 30,000 platelets per microlitre

INITIATION – idiopathic thrombocytopenic purpura contraindicated to splenectomy
Re-assessment required after 3 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has a significant and well-documented contraindication to splenectomy for clinical reasons

and

- ○ Two immunosuppressive therapies have been trialled and failed after therapy of 3 months each (or 1 month for rituximab)

and

- ○ Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microliter

or

- ○ Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Eltrombopag *- continued*

CONTINUATION – idiopathic thrombocytopenic purpura contraindicated to splenectomy
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient's significant contraindication to splenectomy remains

and

- ○ The patient has obtained a response from treatment during the initial approval period

and

- ○ Patient has maintained a platelet count of at least 50,000 platelets per microlitre on treatment

and

- ○ Further treatment with eltrombopag is required to maintain response

INITIATION – severe aplastic anaemia
Re-assessment required after 3 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Two immunosuppressive therapies have been trialled and failed after therapy of at least 3 months duration

and

- ○ Patient has severe aplastic anaemia with a platelet count of less than or equal to 20,000 platelets per microliter

or

- ○ Patient has severe aplastic anaemia with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding

CONTINUATION – severe aplastic anaemia
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has obtained a response from treatment of at least 20,000 platelets per microlitre above baseline during the initial approval period

and

- ○ Platelet transfusion independence for a minimum of 8 weeks during the initial approval period

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Aluminium chloride

INITIATION

Prerequisites (tick box where appropriate)

○ For use as a haemostatis agent

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Emicizumab

INITIATION – Severe Haemophilia A with or without FVIII inhibitors

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ Patient has severe congenital haemophilia A with a severe bleeding phenotype (endogenous factor VIII activity less than or equal to 2%)

and

❍ Emicizumab is to be administered at a dose of no greater than 3 mg/kg weekly for 4 weeks followed by the equivalent of 1.5 mg/kg weekly

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Idarucizumab

INITIATION

Prerequisites (tick box where appropriate)

- ○ For the reversal of the anticoagulant effects of dabigatran when required in situations of life-threatening or uncontrolled bleeding, or for emergency surgery or urgent procedures

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Moroctocog alfa [Recombinant factor VIII]

INITIATION

Prerequisites (tick box where appropriate)

- ○ For patients with haemophilia. Rare Clinical Circumstances Brand of short half-life recombinant factor VIII. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group, subject to criteria

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Octocog alfa [Recombinant factor VIII] (Advate)

INITIATION

Prerequisites (tick box where appropriate)

- ○ For patients with haemophilia. Preferred Brand of short half-life recombinant factor VIII. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Octocog alfa [Recombinant factor VIII] (Kogenate FS)

INITIATION

Prerequisites (tick box where appropriate)

- ○ For patients with haemophilia. Rare Clinical Circumstances Brand of short half-life recombinant factor VIII. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group, subject to criteria

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nonacog gamma

INITIATION

Prerequisites (tick box where appropriate)

- ○ For patients with haemophilia. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rurioctocog alfa pegol [Recombinant factor VIII]

INITIATION

Prerequisites (tick box where appropriate)

- ○ For patients with haemophilia A receiving prophylaxis treatment. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Eftrenonacog alfa

INITIATION

Prerequisites (tick box where appropriate)

- ○ For patients with haemophilia B receiving prophylaxis treatment. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Factor eight inhibitor bypassing fraction

INITIATION

Prerequisites (tick box where appropriate)

- ○ For patients with haemophilia. Preferred Brand of bypassing agent for > 14 days predicted use. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Eptacog alfa

INITIATION

Prerequisites (tick box where appropriate)

- ○ For patients with haemophilia. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group. Rare Clinical Circumstances Brand of bypassing agent for > 14 days predicted use. Access to funded treatment for > 14 days predicted use is by named patient application to the Haemophilia Treaters Group, subject to access criteria

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Bivalirudin

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For use in heparin-induced thrombocytopaenia, heparin resistance or heparin intolerance

or

- ○ For use in patients undergoing endovascular procedures

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Danaparoid

INITIATION

Prerequisites (tick box where appropriate)

- ○ For use in heparin-induced thrombocytopaenia, heparin resistance or heparin intolerance

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Defibrotide

INITIATION

Prerequisites (tick box where appropriate)

❍ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ Patient has moderate or severe sinusoidal obstruction syndrome as a result of chemotherapy or regimen-related toxicities

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Fondaparinux sodium

INITIATION

Prerequisites (tick box where appropriate)

- ○ For use in heparin-induced thrombocytopaenia, heparin resistance or heparin intolerance

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Lysine acetylsalicylate

INITIATION

Prerequisites (tick boxes where appropriate)

○ For use when an immediate antiplatelet effect is required prior to an urgent interventional neuro-radiology or interventional cardiology procedure

and

○ Administration of oral aspirin would delay the procedure

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Eptifibatide

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For use in patients with acute coronary syndromes undergoing percutaneous coronary intervention

or

- ○ For use in patients with definite or strongly suspected intra-coronary thrombus on coronary angiography

or

- ○ For use in patients undergoing intra-cranial intervention

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ticagrelor

INITIATION

Prerequisites (tick box where appropriate)

- ○ Restricted to treatment of acute coronary syndromes specifically for patients who have recently (within the last 60 days) been diagnosed with an ST-elevation or a non-ST-elevation acute coronary syndrome, and in whom fibrinolytic therapy has not been given in the last 24 hours and is not planned

INITIATION – thrombosis prevention neurological stenting

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- ○ Patient has had a neurological stenting procedure* in the last 60 days

or

- ○ Patient is about to have a neurological stenting procedure performed*

and

- ○ Patient has demonstrated clopidogrel resistance using the P2Y12 (VerifyNow) assay or another appropriate platelet function assay and requires antiplatelet treatment with ticagrelor

or

- ○ Clopidogrel resistance has been demonstrated by the occurrence of a new cerebral ischemic event

or

- ○ Clopidogrel resistance has been demonstrated by the occurrence of transient ischemic attack symptoms referable to the stent.

CONTINUATION – thrombosis prevention neurological stenting

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- ○ Patient is continuing to benefit from treatment

and

- ○ Treatment continues to be clinically appropriate

INITIATION – Percutaneous coronary intervention with stent deployment

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- ○ Patient has undergone percutaneous coronary intervention

and

- ○ Patient has had a stent deployed in the previous 4 weeks

and

- ○ Patient is clopidogrel-allergic**

INITIATION – Stent thrombosis

Prerequisites (tick box where appropriate)

- ○ Patient has experienced cardiac stent thrombosis whilst on clopidogrel

INITIATION – Myocardial infarction

Re-assessment required after 1 week

Prerequisites (tick box where appropriate)

- ○ For short term use while in hospital following ST-elevated myocardial infarction

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ticagrelor *- continued*

Note: Indications marked with * are unapproved indications.
Note: Note: ** Clopidogrel allergy is defined as a history of anaphylaxis, urticaria, generalised rash or asthma (in non-asthmatic patients) developing soon after clopidogrel is started and is considered unlikely to be caused by any other treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Plerixafor

INITIATION – Autologous stem cell transplant
Re-assessment required after 3 days
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is to undergo stem cell transplantation

and

- ○ Patient has not had a previous unsuccessful mobilisation attempt with plerixafor

and

- ○ Patient is undergoing G-CSF mobilisation

  and

  - ○ Has a suboptimal peripheral blood CD34 count of less than or equal to 10×10^6/L on day 5 after 4 days of G-CSF treatment

  or

  - ○ Efforts to collect > 1×10^6 CD34 cells/kg have failed after one apheresis procedure

or

- ○ Patient is undergoing chemotherapy and G-CSF mobilisation

  and

  - ○ Has rising white blood cell counts of > 5×10^9/L

    and

    ○ Has a suboptimal peripheral blood CD34 count of less than or equal to 10×10^6/L

  or

  - ○ Efforts to collect > 1×10^6 CD34 cells/kg have failed after one apheresis procedure

  or

  - ○ The peripheral blood CD34 cell counts are decreasing before the target has been received

or

- ○ A previous mobilisation attempt with G-CSF or G-CSF plus chemotherapy has failed

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pegfilgrastim

INITIATION

Prerequisites (tick box where appropriate)

○ For prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk greater than or equal to 5%*)

Note: *Febrile neutropenia risk greater than or equal to 5% after taking into account other risk factors as defined by the European Organisation for Research and Treatment of Cancer (EORTC) guidelines

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Filgrastim

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a haematologist or oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sodium chloride – Inj

INITIATION

Prerequisites (tick box where appropriate)

- ○ For use in flushing of in-situ vascular access devices only

I confirm that the above details are correct:

Signed: ..... Date: .....

Cardiovascular System

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Captopril - Oral liq 5 mg per ml

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For use in children under 12 years of age

or

- ○ For use in tube-fed patients

or

- ○ For management of rebound transient hypertension following cardiac surgery

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sacubitril with valsartan

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient has heart failure

and

- ○ Patient is in NYHA/WHO functional class II

or

- ○ Patient is in NYHA/WHO functional class III

or

- ○ Patient is in NYHA/WHO functional class IV

and

- ○ Patient has a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%

or

- ○ An ECHO is not reasonably practical, and in the opinion of the treating practitioner the patient would benefit from treatment

and

- ○ Patient is receiving concomitant optimal standard chronic heart failure treatments

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adenosine - Inj 3 mg per ml, 10 ml vial

INITIATION

Prerequisites (tick box where appropriate)

- ○ For use in cardiac catheterisation, electrophysiology and MRI

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ajmaline

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a cardiologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ivabradine

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient is indicated for computed tomography coronary angiography

and

- ○ Patient has a heart rate of greater than 70 beats per minute while taking a maximally tolerated dose of beta blocker

or

- ○ Patient is unable to tolerate beta blockers

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Midodrine

INITIATION

Prerequisites (tick box where appropriate)

- ○ Patient has disabling orthostatic hypotension not due to drugs

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nicardipine hydrochloride

INITIATION

Prerequisites (tick boxes where appropriate)

○ Prescribed by, or recommended by an anaesthetist, intensivist, cardiologist or paediatric cardiologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

○ Patient has hypertension requiring urgent treatment with an intravenous agent

or

○ Patient has excessive ventricular afterload

or

○ Patient is awaiting or undergoing cardiac surgery using cardiopulmonary bypass

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Eplerenone

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient has heart failure with ejection fraction less than 40%

and

- ○ Patient is intolerant to optimal dosing of spironolactone

or

- ○ Patient has experienced a clinically significant adverse effect while on optimal dosing of spironolactone

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tolvaptan

INITIATION – autosomal dominant polycystic kidney disease
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a renal physician or any relevant practitioner on the recommendation of a renal physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has a confirmed diagnosis of autosomal dominant polycystic kidney disease

and

- ○ Patient has an estimated glomerular filtration rate (eGFR) of greater than or equal to 25 ml/min/1.73 m^2 at treatment initiation

and

- ○ Patient's disease is rapidly progressing, with a decline in eGFR of greater than or equal to 5 mL/min/1.73 m^2 within one-year

or

- ○ Patient's disease is rapidly progressing, with an average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 m^2 per year over a five-year period

CONTINUATION – autosomal dominant polycystic kidney disease
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a renal physician or any relevant practitioner on the recommendation of a renal physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has not developed end-stage renal disease, defined as an eGFR of less than 15 mL/min/1.73 m^2

and

- ○ Patient has not undergone a kidney transplant

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rosuvastatin

INITIATION – cardiovascular disease risk

Prerequisites (tick boxes where appropriate)

- ○ Patient is considered to be at risk of cardiovascular disease
- **and**
- ○ Patient is Māori or any Pacific ethnicity

or

- ○ Patient has a calculated risk of cardiovascular disease of at least 15% over 5 years
- **and**
- ○ LDL cholesterol has not reduced to less than 1.8 mmol/litre with treatment with the maximum tolerated dose of atorvastatin and/or simvastatin

INITIATION – familial hypercholesterolemia

Prerequisites (tick boxes where appropriate)

- ○ Patient has familial hypercholesterolemia (defined as a Dutch Lipid Criteria score greater than or equal to 6)
- **and**
- ○ LDL cholesterol has not reduced to less than 1.8 mmol/litre with treatment with the maximum tolerated dose of atorvastatin and/or simvastatin

INITIATION – established cardiovascular disease

Prerequisites (tick boxes where appropriate)

- ○ Patient has proven coronary artery disease (CAD)
- **or**
- ○ Patient has proven peripheral artery disease (PAD)
- **or**
- ○ Patient has experienced an ischaemic stroke

and

- ○ LDL cholesterol has not reduced to less than 1.4 mmol/litre with treatment with the maximum tolerated dose of atorvastatin and/or simvastatin

INITIATION – recurrent major cardiovascular events

Prerequisites (tick boxes where appropriate)

- ○ Patient has experienced a recurrent major cardiovascular event (defined as myocardial infarction, ischaemic stroke, coronary revascularisation, hospitalisation for unstable angina) in the last 2 years
- **and**
- ○ LDL cholesterol has not reduced to less than 1.0 mmol/litre with treatment with the maximum tolerated dose of atorvastatin and/or simvastatin

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Levosimendan

INITIATION – Heart transplant

Prerequisites (tick boxes where appropriate)

- ○ For use as a bridge to heart transplant, in patients who have been accepted for transplant

or

- ○ For the treatment of heart failure following heart transplant

INITIATION – Heart failure

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a cardiologist or intensivist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ For the treatment of severe acute decompensated heart failure that is non-responsive to dobutamine

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Alprostadil

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient has erectile dysfunction

and

- ○ Patient is to receive a penile Doppler ultrasonography

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Hydralazine hydrochloride - Tab 25 mg

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For the treatment of refractory hypertension

or

- ○ For the treatment of heart failure, in combination with a nitrate, in patients who are intolerant or have not responded to ACE inhibitors and/or angiotensin receptor blockers

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

bosentan

INITIATION – PAH monotherapy
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pulmonary arterial hypertension (PAH)*

and

- ○ PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- ○ PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV

and

- ○ PAH has been confirmed by right heart catheterisation

and

- ○ A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)

and

- ○ A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

and

- ○ Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm^{-5})

and

- ○ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †

or

- ○ Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- ○ Patient has PAH other than idiopathic / heritable or drug-associated type

or

- ○ Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease

or

- ○ Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- ○ Bosentan is to be used as PAH monotherapy

and

- ○ Patient has experienced intolerable side effects on sildenafil

or

- ○ Patient has an absolute contraindication to sildenafil

or

- ○ Patient is a child with idiopathic PAH or PAH secondary to congenital heart disease

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

bosentan *- continued*

INITIATION – PAH dual therapy
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pulmonary arterial hypertension (PAH)*

and

- ○ PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- ○ PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV

and

- ○ PAH has been confirmed by right heart catheterisation

and

- ○ A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)

and

- ○ A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

and

- ○ Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm^{-5})

and

- ○ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †

or

- ○ Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- ○ Patient has PAH other than idiopathic / heritable or drug-associated type

or

- ○ Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease

or

- ○ Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- ○ Bosentan is to be used as part of PAH dual therapy

and

- ○ Patient has tried a PAH monotherapy (sildenafil) for at least three months and has experienced an inadequate therapeutic response to treatment according to a validated risk stratification tool**

or

- ○ Patient is presenting in NYHA/WHO functional class III or IV, and in the opinion of the treating clinician would likely benefit from initial dual therapy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

bosentan *- continued*

INITIATION – PAH triple therapy
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pulmonary arterial hypertension (PAH)*

and

- ○ PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- ○ PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV

and

- ○ PAH has been confirmed by right heart catheterisation

and

- ○ A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)

and

- ○ A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

and

- ○ Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm^{-5})

and

- ○ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †

or

- ○ Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- ○ Patient has PAH other than idiopathic / heritable or drug-associated type

or

- ○ Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease

or

- ○ Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- ○ Bosentan is to be used as part of PAH triple therapy

and

- ○ Patient is on the lung transplant list

or

- ○ Patient is presenting in NYHA/WHO functional class IV

or

- ○ Patient has tried PAH dual therapy for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool**

and

- ○ Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

bosentan *- continued*

CONTINUATION
Re-assessment required after 2 years
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is continuing to derive benefit from bosentan treatment according to a validated PAH risk stratification tool**

Note: † The European Respiratory Journal Guidelines can be found here: 2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension PAH
** the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ambrisentan

INITIATION – PAH monotherapy
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pulmonary arterial hypertension (PAH)

and

- ○ PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- ○ PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV

and

- ○ PAH has been confirmed by right heart catheterisation

and

- ○ A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)

and

- ○ A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

and

- ○ Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm^{-5})

and

- ○ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †

or

- ○ Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- ○ Patient has PAH other than idiopathic / heritable or drug-associated type

or

- ○ Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease

or

- ○ Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- ○ Ambrisentan is to be used as PAH monotherapy

and

- ○ Patient has experienced intolerable side effects with both sildenafil and bosentan

or

- ○ Patient has an absolute contraindication to sildenafil and an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease)

or

- ○ Patient is a child with idiopathic PAH or PAH secondary to congenital heart disease

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ambrisentan *- continued*

INITIATION – PAH dual therapy
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pulmonary arterial hypertension (PAH)

and

- ○ PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- ○ PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV

and

- ○ PAH has been confirmed by right heart catheterisation

and

- ○ A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)

and

- ○ A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

and

- ○ Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm^{-5})

and

- ○ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †

or

- ○ Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- ○ Patient has PAH other than idiopathic / heritable or drug-associated type

or

- ○ Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease

or

- ○ Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- ○ Ambrisentan is to be used as PAH dual therapy

and

- ○ Patient has tried bosentan (either as PAH monotherapy, or PAH dual therapy with sildenafil) for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool**

or

- ○ Patient has experienced intolerable side effects on bosentan

or

- ○ Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease)

or

- ○ Patient is presenting in NYHA/WHO functional class III or IV, and would benefit from initial dual therapy in the opinion of the treating clinician and has an absolute or relative contraindication to bosentan (eg. due to current liver disease or use of a combined oral contraceptive)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ambrisentan *- continued*

INITIATION – PAH triple therapy
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pulmonary arterial hypertension (PAH)

and

- ○ PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- ○ PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV

and

- ○ PAH has been confirmed by right heart catheterisation

and

- ○ A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)

and

- ○ A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

and

- ○ Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm^{-5})

and

- ○ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †

or

- ○ Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- ○ Patient has PAH other than idiopathic / heritable or drug-associated type

or

- ○ Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease

or

- ○ Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- ○ Ambrisentan is to be used as PAH triple therapy

and

- ○ Patient is on the lung transplant list

or

- ○ Patient is presenting in NYHA/WHO functional class IV

and

- ○ Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease)

or

- ○ Patient has tried PAH dual therapy for at least three months and remains in an unacceptable risk category according to a validated risk stratification tool**

and

- ○ Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ambrisentan *- continued*

CONTINUATION
Re-assessment required after 2 years
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient is continuing to derive benefit from ambrisentan treatment according to a validated PAH risk stratification tool**

Note: † The European Respiratory Journal Guidelines can be found here: 2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension PAH
** the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

sildenafil (Vedafil)

INITIATION – tablets Raynaud's Phenomenon

Prerequisites (tick boxes where appropriate)

- ○ Patient has Raynaud's phenomenon

and

- ○ Patient has severe digital ischaemia (defined as severe pain requiring hospital admission or with a high likelihood of digital ulceration; digital ulcers; or gangrene)

and

- ○ Patient is following lifestyle management (proper body insulation, avoidance of cold exposure, smoking cessation support, avoidance of sympathomimetic drugs)

and

- ○ Patient has persisting severe symptoms despite treatment with calcium channel blockers and nitrates (unless contraindicated or not tolerated)

INITIATION – tablets Pulmonary arterial hypertension

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pulmonary arterial hypertension (PAH)*

and

- ○ PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- ○ PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV

and

- ○ PAH is confirmed by right heart catheterisation

and

- ○ A mean pulmonary artery pressure (PAPm) of greater than 20 mmHg

and

- ○ A pulmonary capillary wedge pressure (PCWP) that is less than or equal to 15 mmHg

and

- ○ Pulmonary vascular resistance (PVR) of at least 2 Wood Units or at least 160 International Units (dyn s cm^{-5})

and

- ○ PAH is non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †

or

- ○ Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- ○ Patient has PAH other than idiopathic / heritable or drug-associated type

or

- ○ Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease

or

- ○ Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

sildenafil (Vedafil) *- continued*

INITIATION – tablets other conditions

Prerequisites (tick boxes where appropriate)

- ○ For use in weaning patients from inhaled nitric oxide

or

- ○ For perioperative use in cardiac surgery patients

or

- ○ For use in intensive care as an alternative to nitric oxide

or

- ○ For use in the treatment of erectile dysfunction secondary to spinal cord injury in patients being treated in a spinal unit

INITIATION – injection

Prerequisites (tick boxes where appropriate)

- ○ For use in the treatment of pulmonary hypertension in infants or children being treated in paediatric intensive care units and neonatal intensive care units when the enteral route is not accessible

and

- ○ For perioperative use following cardiac surgery

or

- ○ For use in persistent pulmonary hypertension of the newborn (PPHN)

or

- ○ For use in congenital diaphragmatic hernia

Note: † The European Respiratory Journal Guidelines can be found here: 2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension PAH
** the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Epoprostenol

INITIATION – PAH dual therapy
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pulmonary arterial hypertension (PAH)

and

- ○ PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- ○ PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class III or IV

and

- ○ PAH has been confirmed by right heart catheterisation

and

- ○ A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)

and

- ○ A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

and

- ○ A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm^{-5})

and

- ○ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †

or

- ○ Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- ○ Patient has PAH other than idiopathic / heritable or drug-associated type

or

- ○ Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease

or

- ○ Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- ○ Epoprostenol is to be used as part of PAH dual therapy with either sildenafil or an endothelin receptor antagonist

and

- ○ Patient is presenting in NYHA/WHO functional class IV

and

- ○ Patient has tried a PAH monotherapy for at least three months and remains in an unacceptable risk category according to a validated risk stratification tool

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Epoprostenol *- continued*

INITIATION – PAH triple therapy
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pulmonary arterial hypertension (PAH)

and

- ○ PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- ○ PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class III or IV

and

- ○ PAH has been confirmed by right heart catheterisation

and

- ○ A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)

and

- ○ A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

and

- ○ A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm^{-5})

and

- ○ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †

or

- ○ Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- ○ Patient has PAH other than idiopathic / heritable or drug-associated type

or

- ○ Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease

or

- ○ Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- ○ Epoprostenol is to be used as PAH triple therapy

and

- ○ Patient is on the lung transplant list

or

- ○ Patient is presenting in NYHA/WHO functional class IV

or

- ○ Patient has tried PAH dual therapy for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool

and

- ○ Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Epoprostenol *- continued*

CONTINUATION
Re-assessment required after 2 years
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is continuing to derive benefit from epoprostenol treatment according to a validated PAH risk stratification tool

Note: † The European Respiratory Journal Guidelines can be found here: 2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension PAH
** the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Iloprost

INITIATION – PAH monotherapy
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pulmonary arterial hypertension (PAH)

and

- ○ PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- ○ PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV

and

- ○ PAH has been confirmed by right heart catheterisation

and

- ○ A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)

and

- ○ A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

and

- ○ A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm^{-5})

and

- ○ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †

or

- ○ Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- ○ Patient has PAH other than idiopathic / heritable or drug-associated type

or

- ○ Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease

or

- ○ Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- ○ Iloprost is to be used as PAH monotherapy

and

- ○ Patient has experienced intolerable side effects on sildenafil and both the funded endothelin receptor antagonists (i.e. both bosentan and ambrisentan)

or

- ○ Patient has an absolute contraindication to sildenafil and an absolute or relative contraindication to endothelin receptor antagonists

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Iloprost *- continued*

INITIATION – PAH dual therapy
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pulmonary arterial hypertension (PAH)

and

- ○ PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- ○ PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV

and

- ○ PAH has been confirmed by right heart catheterisation

and

- ○ A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)

and

- ○ A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

and

- ○ A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm^{-5})

and

- ○ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †

or

- ○ Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- ○ Patient has PAH other than idiopathic / heritable or drug-associated type

or

- ○ Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease

or

- ○ Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- ○ Iloprost is to be used as PAH dual therapy with either sildenafil or an endothelin receptor antagonist

and

- ○ Patient has an absolute contraindication to or has experienced intolerable side effects on sildenafil

or

- ○ Patient has an absolute or relative contraindication to or experienced intolerable side effects with a funded endothelin receptor antagonist

and

- ○ Patient has tried a PAH monotherapy for at least three months and remains in an unacceptable risk category according to a validated risk stratification tool**

or

- ○ Patient is presenting in NYHA/WHO functional class III or IV, and in the opinion of the treating clinician would benefit from initial dual therapy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Iloprost *- continued*

INITIATION – PAH triple therapy
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pulmonary arterial hypertension (PAH)

and

- ○ PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications

and

- ○ PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV

and

- ○ PAH has been confirmed by right heart catheterisation

and

- ○ A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair)

and

- ○ A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg

and

- ○ A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm^{-5})

and

- ○ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †

or

- ○ Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**

or

- ○ Patient has PAH other than idiopathic / heritable or drug-associated type

or

- ○ Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease

or

- ○ Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures

and

- ○ Iloprost is to be used as PAH triple therapy

and

- ○ Patient is on the lung transplant list

or

- ○ Patient is presenting in NYHA/WHO functional class IV

or

- ○ Patient has tried PAH dual therapy for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool**

and

- ○ Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Iloprost *- continued*

CONTINUATION
Re-assessment required after 2 years
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is continuing to derive benefit from iloprost treatment according to a validated PAH risk stratification tool

Note: † The European Respiratory Journal Guidelines can be found here: 2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension PAH
** the requirement to use a validated risk stratification tool to determine insufficient response applies to adults. Determining insufficient response in children does not require use of a validated PAH risk stratification tool, where currently no such validated tools exist for PAH risk stratification in children.

I confirm that the above details are correct:

Signed: ..... Date: .....

Dermatologicals

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Mafenide acetate

INITIATION

Prerequisites (tick box where appropriate)

- ○ For the treatment of burns patients

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Betamethasone valerate with clioquinol

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For the treatment of intertrigo

or

- ○ For continuation use

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pimecrolimus

INITIATION

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a dermatologist, paediatrician or ophthalmologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ Patient has atopic dermatitis on the eyelid

and

❍ Patient has at least one of the following contraindications to topical corticosteroids: periorificial dermatitis, rosacea, documented epidermal atrophy, documented allergy to topical corticosteroids, cataracts, glaucoma, or raised intraocular pressure

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tacrolimus Ointment

INITIATION

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a dermatologist or paediatrician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ Patient has atopic dermatitis on the face

and

❍ Patient has at least one of the following contraindications to topical corticosteroids: periorificial dermatitis, rosacea, documented epidermal atrophy or documented allergy to topical corticosteroids

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Methyl aminolevulinate hydrochloride

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a dermatologist or plastic surgeon, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Genito-Urinary System

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Terbutaline

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by an obstetrician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Finasteride

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient has symptomatic benign prostatic hyperplasia

and

or

- ○ The patient is intolerant of non-selective alpha blockers or these are contraindicated
- ○ Symptoms are not adequately controlled with non-selective alpha blockers

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tamsulosin

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient has symptomatic benign prostatic hyperplasia

and

- ○ The patient is intolerant of non-selective alpha blockers or these are contraindicated

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Potassium citrate

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ The patient has recurrent calcium oxalate urolithiasis

and

- ○ The patient has had more than two renal calculi in the two years prior to the application

I confirm that the above details are correct:

Signed: ..... Date: .....

Hormone Preparations

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Oxandrolone - Tab 2.5 mg

INITIATION

Prerequisites (tick box where appropriate)

○ For the treatment of burns patients

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Cinacalcet

INITIATION – parathyroid carcinoma or calciphylaxis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a nephrologist or endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has been diagnosed with a parathyroid carcinoma (see Note)

and

- ○ The patient has persistent hypercalcaemia (serum calcium greater than or equal to 3 mmol/L) despite previous first-line treatments including sodium thiosulfate (where appropriate) and bisphosphonates

and

- ○ The patient is symptomatic

or

- ○ The patient has been diagnosed with calciphylaxis (calcific uraemic arteriolopathy)

and

- ○ The patient has symptomatic (e.g. painful skin ulcers) hypercalcaemia (serum calcium greater than or equal to 3 mmol/L)

and

- ○ The patient's condition has not responded to previous first-line treatments including bisphosphonates and sodium thiosulfate

CONTINUATION – parathyroid carcinoma or calciphylaxis
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a nephrologist or endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient's serum calcium level has fallen to < 3mmol/L

and

- ○ The patient has experienced clinically significant symptom improvement

Note: This does not include parathyroid adenomas unless these have become malignant.

INITIATION – primary hyperparathyroidism
Prerequisites (tick boxes where appropriate)

- ○ Patient has primary hyperparathyroidism

and

- ○ Patient has hypercalcaemia of more than 3 mmol/L with or without symptoms

or

- ○ Patient has hypercalcaemia of more than 2.85 mmol/L with symptoms

and

- ○ Surgery is not feasible or has failed

and

- ○ Patient has other comorbidities, severe bone pain, or calciphylaxis

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Cinacalcet *- continued*

INITIATION – secondary or tertiary hyperparathyroidism
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has tertiary hyperparathyroidism and markedly elevated parathyroid hormone (PTH) with hypercalcaemia
- **or**
- ○ Patient has symptomatic secondary hyperparathyroidism and elevated PTH

and

- ○ Patient is on renal replacement therapy

and

- ○ Residual parathyroid tissue has not been localised despite repeat unsuccessful parathyroid explorations
- **or**
- ○ Parathyroid tissue is surgically inaccessible
- **or**
- ○ Parathyroid surgery is not feasible

CONTINUATION – secondary or tertiary hyperparathyroidism
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has had a kidney transplant, and following a treatment free interval of at least 12 weeks a clinically acceptable parathyroid hormone (PTH) level to support ongoing cessation of treatment has not been reached
- **or**
- ○ The patient has not received a kidney transplant and trial of withdrawal of cinacalcet is clinically inappropriate

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Cabergoline

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Inhibition of lactation

or

- ○ Patient has hyperprolactinemia

or

- ○ Patient has acromegaly

Note: Indication marked with * is an unapproved indication.

I confirm that the above details are correct:

Signed: ..... Date: .....

RS1826 - Somatropin

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Somatropin

INITIATION – growth hormone deficiency in children
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Growth hormone deficiency causing symptomatic hypoglycaemia, or with other significant growth hormone deficient sequelae (e.g. cardiomyopathy, hepatic dysfunction) and diagnosed with GH < 5 mcg/l on at least two random blood samples in the first 2 weeks of life, or from samples during established hypoglycaemia (whole blood glucose < 2 mmol/l using a laboratory device)

or

- ○ Height velocity < 25th percentile for age; and adjusted for bone age/pubertal status if appropriate over 6 or 12 months using the standards of Tanner and Davies (1985)

and

- ○ A current bone age is < 14 years (female patients) or < 16 years (male patients)

and

- ○ Peak growth hormone value of < 5.0 mcg per litre in response to two different growth hormone stimulation tests. In children who are 5 years or older, GH testing with sex steroid priming is required

and

- ○ If the patient has been treated for a malignancy, they should be disease free for at least one year based upon follow-up laboratory and radiological imaging appropriate for the malignancy, unless there are strong medical reasons why this is either not necessary or appropriate

and

- ○ Appropriate imaging of the pituitary gland has been obtained

CONTINUATION – growth hormone deficiency in children
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ A current bone age is 14 years or under (female patients) or 16 years or under (male patients)

and

- ○ Height velocity is greater than or equal to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth hormone treatment, as calculated over six months using the standards of Tanner and Davis (1985)

and

- ○ Height velocity is greater than or equal to 2.0 cm per year, as calculated over 6 months

and

- ○ No serious adverse effect that the patients specialist considers is likely to be attributable to growth hormone treatment has occurred

and

- ○ No malignancy has developed since starting growth hormone

INITIATION – Turner syndrome
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a post-natal genotype confirming Turner Syndrome

and

- ○ Height velocity is < 25th percentile over 6-12 months using the standards of Tanner and Davies (1985)

and

- ○ A current bone age is < 14 years

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Somatropin *- continued*

CONTINUATION – Turner syndrome
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Height velocity greater than or equal to 50th percentile for age (while on growth hormone calculated over 6 to 12 months using the Ranke's Turner Syndrome growth velocity charts)

and

- ○ Height velocity is greater than or equal to 2 cm per year, calculated over six months

and

- ○ A current bone age is 14 years or under

and

- ○ No serious adverse effect that the specialist considers is likely to be attributable to growth hormone treatment has occurred

and

- ○ No malignancy has developed since starting growth hormone

INITIATION – short stature without growth hormone deficiency
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient's height is more than 3 standard deviations below the mean for age or for bone age if there is marked growth acceleration or delay

and

- ○ Height velocity is < 25th percentile for age (adjusted for bone age/pubertal status if appropriate), as calculated over 6 to 12 months using the standards of Tanner and Davies(1985)

and

- ○ A current bone age is < 14 years (female patients) or < 16 years (male patients)

and

- ○ The patient does not have severe chronic disease (including malignancy or recognized severe skeletal dysplasia) and is not receiving medications known to impair height velocity

CONTINUATION – short stature without growth hormone deficiency
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Height velocity is greater than or equal to 50th percentile (adjusted for bone age/pubertal status if appropriate) as calculated over 6 to 12 months using the standards of Tanner and Davies (1985)

and

- ○ Height velocity is greater than or equal to 2 cm per year as calculated over six months

and

- ○ Current bone age is 14 years or under (female patients) or 16 years or under (male patients)

and

- ○ No serious adverse effect that the patient's specialist considers is likely to be attributable to growth hormone treatment has occurred

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Somatropin *- continued*

INITIATION – short stature due to chronic renal insufficiency
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an endocrinologist, paediatric endocrinologist or renal physician on the recommendation of a endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient's height is more than 2 standard deviations below the mean

and

- ○ Height velocity is < 25th percentile (adjusted for bone age/pubertal status if appropriate) as calculated over 6 to 12 months using the standards of Tanner and Davies (1985)

and

- ○ A current bone age is to 14 years or under (female patients) or to 16 years or under (male patients)

and

- ○ The patient is metabolically stable, has no evidence of metabolic bone disease and absence of any other severe chronic disease

and

- ○ The patient is under the supervision of a specialist with expertise in renal medicine

and

- ○ The patient has a GFR less than or equal to 30 ml/min/1.73 m^2 as measured by the Schwartz method (Height(cm)/plasma creatinine (umol/l × 40 = corrected GFR (ml/min/1.73 m^2) in a child who may or may not be receiving dialysis

or

- ○ The patient has received a renal transplant and has received < 5mg/ m^2 /day of prednisone or equivalent for at least 6 months

CONTINUATION – short stature due to chronic renal insufficiency
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an endocrinologist, paediatric endocrinologist or renal physician on the recommendation of a endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Height velocity is greater than or equal to 50th percentile (adjusted for bone age/pubertal status if appropriate) as calculated over 6 to 12 months using the standards of Tanner and Davies (1985)

and

- ○ Height velocity is greater than or equal to 2 cm per year as calculated over six months

and

- ○ A current bone age is 14 years or under (female patients) or 16 years or under (male patients)

and

- ○ No serious adverse effect that the patients specialist considers is likely to be attributable to growth hormone has occurred

and

- ○ No malignancy has developed after growth hormone therapy was commenced

and

- ○ The patient has not experienced significant biochemical or metabolic deterioration confirmed by diagnostic results

and

- ○ The patient has not received renal transplantation since starting growth hormone treatment

and

- ○ If the patient requires transplantation, growth hormone prescription should cease before transplantation and a new application should be made after transplantation based on the above criteria

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Somatropin *- continued*

INITIATION – Prader-Willi syndrome
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a diagnosis of Prader-Willi syndrome that has been confirmed by genetic testing or clinical scoring criteria

and

- ○ The patient is aged six months or older

and

- ○ A current bone age is < 14 years (female patients) or < 16 years (male patients)

and

- ○ Sleep studies or overnight oximetry have been performed and there is no obstructive sleep disorder requiring treatment, or if an obstructive sleep disorder is found, it has been adequately treated under the care of a paediatric respiratory physician and/or ENT surgeon

and

- ○ The patient is aged two years or older

and

- ○ There is no evidence of type II diabetes or uncontrolled obesity defined by BMI that has increased by greater than or equal to 0.5 standard deviations in the preceding 12 months

or

- ○ The patient is aged between six months and two years and a thorough upper airway assessment is planned to be undertaken prior to treatment commencement and at six to 12 weeks following treatment initiation

CONTINUATION – Prader-Willi syndrome
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Height velocity is greater than or equal to 50th percentile (adjusted for bone age/pubertal status if appropriate) as calculated over 6 to 12 months using the standards of Tanner and Davies (1985)

and

- ○ Height velocity is greater than or equal to 2 cm per year as calculated over six months

and

- ○ A current bone age is 14 years or under (female patients) or 16 years or under (male patients)

and

- ○ No serious adverse effect that the patient's specialist con siders is likely to be attributable to growth hormone treatment has occurred

and

- ○ No malignancy has developed after growth hormone therapy was commenced

and

- ○ The patient has not developed type II diabetes or uncontrolled obesity as defined by BMI that has increased by greater than or equal to 0.5 standard deviations in the preceding 12 months

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Somatropin *- continued*

INITIATION – adults and adolescents
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ The patient has a medical condition that is known to cause growth hormone deficiency (e.g. surgical removal of the pituitary for treatment of a pituitary tumour)

and

❍ The patient has undergone appropriate treatment of other hormonal deficiencies and psychological illnesses

and

❍ The patient has severe growth hormone deficiency (see notes)

and

❍ The patient's serum IGF-I is more than 1 standard deviation below the mean for age and sex

and

❍ The patient has poor quality of life, as defined by a score of 16 or more using the disease-specific quality of life questionnaire for adult growth hormone deficiency (QoL-AGHDA®)

Note: For the purposes of adults and adolescents, severe growth hormone deficiency is defined as a peak serum growth hormone level of less than or equal to 3 mcg per litre during an adequately performed insulin tolerance test (ITT) or glucagon stimulation test.
Patients with one or more additional anterior pituitary hormone deficiencies and a known structural pituitary lesion only require one test. Patients with isolated growth hormone deficiency require two growth hormone stimulation tests, of which, one should be ITT unless otherwise contraindicated. Where an additional test is required, an arginine provocation test can be used with a peak serum growth hormone level of less than or equal to 0.4 mcg per litre.
The dose of somatropin should be started at 0.2 mg daily and be titrated by 0.1 mg monthly until it is within 1 standard deviation of the mean normal value for age and sex; and
The dose of somatropin not to exceed 0.7 mg per day for male patients, or 1 mg per day for female patients.
At the commencement of treatment for hypopituitarism, patients must be monitored for any required adjustment in replacement doses of corticosteroid and levothyroxine.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Somatropin *- continued*

CONTINUATION – adults and adolescents
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an endocrinologist or paediatric endocrinologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has been treated with somatropin for < 12 months
- **and**
- ○ There has been an improvement in the Quality of Life Assessment defined as a reduction of at least 8 points on the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA®) score from baseline
- **and**
- ○ Serum IGF-I levels have increased to within ±1SD of the mean of the normal range for age and sex
- **and**
- ○ The dose of somatropin does not exceed 0.7 mg per day for male patients, or 1 mg per day for female patients

or

- ○ The patient has been treated with somatropin for more than 12 months
- **and**
- ○ The patient has not had a deterioration in Quality of Life defined as a 6 point or greater increase from their lowest QoL-AGHDA® score on treatment (other than due to obvious external factors such as external stressors)
- **and**
- ○ Serum IGF-I levels have continued to be maintained within ±1SD of the mean of the normal range for age and sex (other than for obvious external factors)
- **and**
- ○ The dose of somatropin has not exceeded 0.7 mg per day for male patients or 1 mg per day for female patients

or

- ○ The patient has had a Special Authority approval for somatropin for childhood deficiency in children and no longer meets the renewal criteria under this indication
- **and**
- ○ The patient has undergone appropriate treatment of other hormonal deficiencies and psychological illnesses
- **and**
- ○ The patient has severe growth hormone deficiency (see notes)
- **and**
- ○ The patient's serum IGF-I is more than 1 standard deviation below the mean for age and sex
- **and**
- ○ The patient has poor quality of life, as defined by a score of 16 or more using the disease-specific quality of life questionnaire for adult growth hormone deficiency (QoL-AGHDA®)

Note: For the purposes of adults and adolescents, severe growth hormone deficiency is defined as a peak serum growth hormone level of less than or equal to 3 mcg per litre during an adequately performed insulin tolerance test (ITT) or glucagon stimulation test.
Patients with one or more additional anterior pituitary hormone deficiencies and a known structural pituitary lesion only require one test. Patients with isolated growth hormone deficiency require two growth hormone stimulation tests, of which, one should be ITT unless otherwise contraindicated. Where an additional test is required, an arginine provocation test can be used with a peak serum growth hormone level of less than or equal to 0.4 mcg per litre.
The dose of somatropin should be started at 0.2 mg daily and be titrated by 0.1 mg monthly until the serum IGF-I is within 1 standard deviation of the mean normal value for age and sex; and
The dose of somatropin not to exceed 0.7 mg per day for male patients, or 1 mg per day for female patients.
At the commencement of treatment for hypopituitarism, patients must be monitored for any required adjustment in replacement doses of corticosteroid and levothyroxine.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Liothyronine sodium - Tab 20 mcg

INITIATION

Prerequisites (tick box where appropriate)

- ○ For a maximum of 14 days' treatment in patients with thyroid cancer who are due to receive radioiodine therapy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Propylthiouracil

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ The patient has hyperthyroidism

and

- ○ The patient is intolerant of carbimazole or carbimazole is contraindicated

I confirm that the above details are correct:

Signed: ..... Date: .....

Infections

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Streptomycin sulphate

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Amikacin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tobramycin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tobramycin Solution for inhalation 60 mg per ml, 5 ml

INITIATION

Prerequisites (tick box where appropriate)

○ Patient has cystic fibrosis

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tobramcyin

INITIATION

Prerequisites (tick box where appropriate)

○ For addition to orthopaedic bone cement

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Paromomycin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Imipenem with cilastatin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ertapenem

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Meropenem

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ceftazidime with avibactam

INITIATION

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital

and

❍ Proven infection with a carbapenem-resistant micro-organism, based on microbiology report

or

❍ Probable infection with a carbapenem-resistant micro-organism, based on assessment by a clinical microbiologist or infectious disease specialist.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ceftazadime

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Cefepime

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ceftaroline

INITIATION – multi-resistant organisn salvage therapy

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ For patients where alternative therapies have failed

or

❍ For patients who have a contraindication or hypersensitivity to standard current therapies

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Roxithromycin tab dispersible 50 mg

INITIATION

Prerequisites (tick box where appropriate)

○ Only for use in patients under 12 years of age

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Clarithromycin

INITIATION – Tab 250 mg and oral liquid

Prerequisites (tick boxes where appropriate)

- ○ Atypical mycobacterial infection

or

- ○ Mycobacterium tuberculosis infection where there is drug resistance or intolerance to standard pharmaceutical agents

or

- ○ Helicobacter pylori eradication

or

- ○ Prophylaxis of infective endocarditis associated with surgical or dental procedures if amoxicillin is contra-indicated

INITIATION – Tab 500 mg

Prerequisites (tick box where appropriate)

- ○ Helicobacter pylori eradication

INITIATION – Infusion

Prerequisites (tick boxes where appropriate)

- ○ Atypical mycobacterial infection

or

- ○ Mycobacterium tuberculosis infection where there is drug resistance or intolerance to standard pharmaceutical agents

or

- ○ Community-acquired pneumonia

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Azithromycin

INITIATION – bronchiolitis obliterans syndrome, cystic fibrosis and atypical Mycobacterium infections

Prerequisites (tick boxes where appropriate)

- ○ Patient has received a lung transplant, stem cell transplant or bone marrow transplant and requires treatment for bronchiolitis obliterans syndrome*

or

- ○ Patient has received a lung transplant and requires prophylaxis for bronchiolitis obliterans syndrome*

or

- ○ Patient has cystic fibrosis and has chronic infection with Pseudomonas aeruginosa or Pseudomonas related gram negative organisms*

or

- ○ Patient has an atypical Mycobacterium infection

Note: Indications marked with * are unapproved indications

INITIATION – non-cystic fibrosis bronchiectasis*

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist or paediatrician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ For prophylaxis of exacerbations of non-cystic fibrosis bronchiectasis*

and

- ○ Patient is aged 18 and under

and

- ○ Patient has had 3 or more exacerbations of their bronchiectasis, within a 12 month period

or

- ○ Patient has had 3 acute admissions to hospital for treatment of infective respiratory exacerbations within a 12 month period

Note: Indications marked with * are unapproved indications. A maximum of 24 months of azithromycin treatment for non-cystic fibrosis will be subsidised in the community.

CONTINUATION – non-cystic fibrosis bronchiectasis*

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist or paediatrician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has completed 12 months of azithromycin treatment for non-cystic fibrosis bronchiectasis

and

- ○ Following initial 12 months of treatment, the patient has not received any further azithromycin treatment for non-cystic fibrosis bronchiectasis for a further 12 months, unless considered clinically inappropriate to stop treatment

and

- ○ The patient will not receive more than a total of 24 months' azithromycin cumulative treatment (see note)

Note: Indications marked with * are unapproved indications. A maximum of 24 months of azithromycin treatment for non-cystic fibrosis will be subsidised in the community.

INITIATION – other indications

Re-assessment required after 5 days

Prerequisites (tick box where appropriate)

- ○ For any other condition

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Azithromycin *- continued*

CONTINUATION – other indications
Re-assessment required after 5 days
Prerequisites (tick box where appropriate)

○ For any other condition

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ticarcillin with clavulanic acid

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Piperacillin with tazobactam

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ciprofloxacin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Moxifloxacin

INITIATION – Mycobacterium infection

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an infectious disease specialist, clinical microbiologist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Active tuberculosis

and

- ○ Documented resistance to one or more first-line medications

or

- ○ Suspected resistance to one or more first-line medications (tuberculosis assumed to be contracted in an area with known resistance), as part of regimen containing other second-line agents

or

- ○ Impaired visual acuity (considered to preclude ethambutol use)

or

- ○ Significant pre-existing liver disease or hepatotoxicity from tuberculosis medications

or

- ○ Significant documented intolerance and/or side effects following a reasonable trial of first-line medications

or

- ○ Mycobacterium avium-intracellulare complex not responding to other therapy or where such therapy is contraindicated

or

- ○ Patient is under five years of age and has had close contact with a confirmed multi-drug resistant tuberculosis case

INITIATION – Pneumonia

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an infectious disease specialist or clinical microbiologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Immunocompromised patient with pneumonia that is unresponsive to first-line treatment

or

- ○ Pneumococcal pneumonia or other invasive pneumococcal disease highly resistant to other antibiotics

INITIATION – Penetrating eye injury

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by an ophthalmologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Five days treatment for patients requiring prophylaxis following a penetrating eye injury

INITIATION – Mycoplasma genitalium

Prerequisites (tick boxes where appropriate)

- ○ Has nucleic acid amplification test (NAAT) confirmed Mycoplasma genitalium and is symptomatic

and

- ○ Has tried and failed to clear infection using azithromycin

or

- ○ Has laboratory confirmed azithromycin resistance

and

- ○ Treatment is only for 7 days

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Moxifloxacin *- continued*

INITIATION – severe delayed beta-lactam allergy

Prerequisites (tick box where appropriate)

❍ Prescribed by, or recommended by an infectious disease specialist or clinical microbiologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ Individual has a history of severe delayed beta-lactam allergy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tigecycline

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Daptomycin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Lincomycin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Linezolid

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sulphadiazine

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or maternal-foetal medicine specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Teicoplanin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Fosfomycin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pivmecillinam

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Vancomycin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Aztreonam, Chloramphenicol

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Clindamycin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Fusidic acid

INITIATION

Prerequisites (tick box where appropriate)

○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Colistin sulphomethate [Colestimethate]

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ketoconazole - Tab 200 mg

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by an oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Amphotericin B - Inj (liposomal) 50 mg vial

INITIATION

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a clinical microbiologist, haematologist, infectious disease specialist, oncologist, respiratory specialist or transplant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ Proven or probable invasive fungal infection, to be prescribed under an established protocol

or

❍ Possible invasive fungal infection

and

❍ A multidisciplinary team (including an infectious disease physician or a clinical microbiologist) considers the treatment to be appropriate

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Amphotericin B - Inj 50 mg vial

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, haematologist, infectious disease specialist, oncologist, respiratory specialist or transplant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Fluconazole

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a consultant, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Itraconazole

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical immunologist, clinical microbiologist, dermatologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Voriconazole

INITIATION – Proven or probable aspergillus infection

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, haematologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is immunocompromised

and

- ○ Patient has proven or probable invasive aspergillus infection

INITIATION – Possible aspergillus infection

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, haematologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is immunocompromised

and

- ○ Patient has possible invasive aspergillus infection

and

- ○ A multidisciplinary team (including an infectious disease physician) considers the treatment to be appropriate

INITIATION – Resistant candidiasis infections and other moulds

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, haematologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is immunocompromised

and

- ○ Patient has fluconazole resistant candidiasis

or

- ○ Patient has mould strain such as Fusarium spp. and Scedosporium spp

and

- ○ A multidisciplinary team (including an infectious disease physician or clinical microbiologist) considers the treatment to be appropriate

INITIATION – Invasive fungal infection prophylaxis

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient is at risk of invasive fungal infection

and

- ○ Voriconazole is prescribed by, or recommended by a haematologist, transplant physician, infectious disease specialist, paediatric haematologist or paediatric oncologist

or

- ○ Prescribing voriconazole is in accordance with a protocol or guideline that has been endorsed by the Health New Zealand - Te Whatu Ora Hospital in the specific settings where there is a greater than 10% risk of invasive fungal infection (IFI)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Voriconazole *- continued*

CONTINUATION – Invasive fungal infection prophylaxis
Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ The patient is at risk of invasive fungal infection

and

❍ Voriconazole is prescribed by, or recommended by a haematologist, transplant physician, infectious disease specialist, paediatric haematologist or paediatric oncologist

or

❍ Prescribing voriconazole is in accordance with a protocol or guideline that has been endorsed by the Health New Zealand - Te Whatu Ora Hospital in the specific settings where there is a greater than 10% risk of invasive fungal infection (IFI)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Posaconazole

INITIATION
Re-assessment required after 6 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has acute myeloid leukaemia

or

- ○ Patient is planned to receive a stem cell transplant and is at high risk for aspergillus infection

and

- ○ Patient is to be treated with high dose remission induction therapy or re-induction therapy

CONTINUATION
Re-assessment required after 6 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has previously received posaconazole prophylaxis during remission induction therapy

and

- ○ Patient is to be treated with high dose remission re-induction therapy

or

- ○ Patient is to be treated with high dose consolidation therapy

or

- ○ Patient is receiving a high risk stem cell transplant

INITIATION – Invasive fungal infection prophylaxis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient is at risk of invasive fungal infection

and

- ○ Posaconazole is prescribed by, or recommended by a haematologist, transplant physician, infectious disease specialist, paediatric haematologist or paediatric oncologist

or

- ○ Prescribing posaconazole is in accordance with a protocol or guideline that has been endorsed by the Health New Zealand - Te Whatu Ora Hospital in the specific settings where there is a greater than 10% risk of invasive fungal infection (IFI)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Posaconazole *- continued*

CONTINUATION – Invasive fungal infection prophylaxis
Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ The patient is at risk of invasive fungal infection

and

❍ Posaconazole is prescribed by, or recommended by a haematologist, transplant physician, infectious disease specialist, paediatric haematologist or paediatric oncologist

or

❍ Prescribing posaconazole is in accordance with a protocol or guideline that has been endorsed by the Health New Zealand - Te Whatu Ora Hospital in the specific settings where there is a greater than 10% risk of invasive fungal infection (IFI)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Flucytosine

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Caspofungin

INITIATION

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a clinical microbiologist, haematologist, infectious disease specialist, oncologist, respiratory specialist or transplant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ Proven or probable invasive fungal infection, to be prescribed under an established protocol

or

❍ Possible invasive fungal infection

and

❍ A multidisciplinary team (including an infectious disease physician or a clinical microbiologist) considers the treatment to be appropriate

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Clofazimine

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, dermatologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Dapsone

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, dermatologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Cycloserine

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Isoniazid with rifampicin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, dermatologist, paediatrician, public health physician or internal medicine physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pyrazinamide

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rifampicin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, dermatologist, internal medicine physician, paediatrician or public health physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Bedaquiline

INITIATION – multi-drug resistant tuberculosis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ❍ The person has multi-drug resistant tuberculosis (MDR-TB)

and

- ❍ Ministry of Health's Tuberculosis Clinical Network has reviewed the individual case and recommends bedaquiline as part of the treatment regimen

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Isoniazid

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, dermatologist, paediatrician, public health physician or internal medicine physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rifabutin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, gastroenterologist, infectious disease specialist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ethambutol hydrochloride

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Para-aminosalicylic Acid

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Protionamide

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Albendazole

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ivermectin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, dermatologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Artemether with lumefantrine

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Artesunate

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Atovaquone with proguanil hydrochloride

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Chloroquine phosphate

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, dermatologist, infectious disease specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Mefloquine hydrochloride

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, dermatologist, infectious disease specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pentamidine isethionate

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Primaquine phosphate

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pyrimethamine

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist or maternal-foetal medicine specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Quinine dihydrochloride

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sodium stibogluconate

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Spiramycin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a maternal-foetal medicine specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nitazoxanide

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Non-Nucleoside Reverse Transcriptase Inhibitors

INITIATION – Confirmed HIV

Prerequisites (tick box where appropriate)

- ○ Patient has confirmed HIV infection

INITIATION – Prevention of maternal transmission

Prerequisites (tick boxes where appropriate)

- ○ Prevention of maternal foetal transmission

or

- ○ Treatment of the newborn for up to eight weeks

INITIATION – Post-exposure prophylaxis following exposure to HIV

Prerequisites (tick boxes where appropriate)

- ○ Treatment course to be initiated within 72 hours post exposure

and

- ○ Patient has had condomless anal intercourse or receptive vaginal intercourse with a known HIV positive person with an unknown or detectable viral load greater than 200 copies per ml

or

- ○ Patient has shared intravenous injecting equipment with a known HIV positive person

or

- ○ Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required

or

- ○ Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines for PEP (https://www.ashm

INITIATION – Percutaneous exposure

Prerequisites (tick box where appropriate)

- ○ Patient has percutaneous exposure to blood known to be HIV positive

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nucleoside Reverse Transcriptase Inhibitors

INITIATION – Confirmed HIV

Prerequisites (tick box where appropriate)

- ○ Patient has confirmed HIV infection

INITIATION – Prevention of maternal transmission

Prerequisites (tick boxes where appropriate)

- ○ Prevention of maternal foetal transmission

or

- ○ Treatment of the newborn for up to eight weeks

INITIATION – Post-exposure prophylaxis following exposure to HIV

Prerequisites (tick boxes where appropriate)

- ○ Treatment course to be initiated within 72 hours post exposure

and

- ○ Patient has had condomless anal intercourse or receptive vaginal intercourse with a known HIV positive person with an unknown or detectable viral load greater than 200 copies per ml

or

- ○ Patient has shared intravenous injecting equipment with a known HIV positive person

or

- ○ Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required

or

- ○ Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines for PEP (https://www.ashm

INITIATION – Percutaneous exposure

Prerequisites (tick box where appropriate)

- ○ Patient has percutaneous exposure to blood known to be HIV positive

I confirm that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Protease Inhibitors

INITIATION – Confirmed HIV

Prerequisites (tick box where appropriate)

- ○ Patient has confirmed HIV infection

INITIATION – Prevention of maternal transmission

Prerequisites (tick boxes where appropriate)

- ○ Prevention of maternal foetal transmission

or

- ○ Treatment of the newborn for up to eight weeks

INITIATION – Post-exposure prophylaxis following exposure to HIV

Prerequisites (tick boxes where appropriate)

- ○ Treatment course to be initiated within 72 hours post exposure

and

- ○ Patient has had condomless anal intercourse or receptive vaginal intercourse with a known HIV positive person with an unknown or detectable viral load greater than 200 copies per ml

or

- ○ Patient has shared intravenous injecting equipment with a known HIV positive person

or

- ○ Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required

or

- ○ Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines for PEP (https://www.ashm

INITIATION – Percutaneous exposure

Prerequisites (tick box where appropriate)

- ○ Patient has percutaneous exposure to blood known to be HIV positive

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Strand Transfer Inhibitors

INITIATION – Confirmed HIV

Prerequisites (tick box where appropriate)

- ○ Patient has confirmed HIV infection

INITIATION – Prevention of maternal transmission

Prerequisites (tick boxes where appropriate)

- ○ Prevention of maternal foetal transmission

or

- ○ Treatment of the newborn for up to eight weeks

INITIATION – Post-exposure prophylaxis following exposure to HIV

Prerequisites (tick boxes where appropriate)

- ○ Treatment course to be initiated within 72 hours post exposure

and

- ○ Patient has had condomless anal intercourse or receptive vaginal intercourse with a known HIV positive person with an unknown or detectable viral load greater than 200 copies per ml

or

- ○ Patient has shared intravenous injecting equipment with a known HIV positive person

or

- ○ Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required

or

- ○ Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines for PEP (https://www.ashm

INITIATION – Percutaneous exposure

Prerequisites (tick box where appropriate)

- ○ Patient has percutaneous exposure to blood known to be HIV positive

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ledipasvir with sofosbuvir

Note: Only for use in patients with approval by the Hepatitis C Treatment Panel (HepCTP). Applications will be considered by HepCTP at its regular meetings and approved subject to eligibility according to the Access Criteria (set out in Section B of the Pharmaceutical Schedule).

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Cidofovir

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist, infectious disease specialist, otolaryngologist or oral surgeon, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Foscarnet sodium

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ganciclovir

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a clinical microbiologist or infectious disease specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Valganciclovir

INITIATION – Transplant cytomegalovirus prophylaxis
Re-assessment required after 3 months
Prerequisites (tick box where appropriate)

- ○ Patient has undergone a solid organ transplant and requires valganciclovir for CMV prophylaxis

CONTINUATION – Transplant cytomegalovirus prophylaxis
Re-assessment required after 3 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has undergone a solid organ transplant and received anti-thymocyte globulin and requires valganciclovir therapy for CMV prophylaxis
- **and**
- ○ Patient is to receive a maximum of 90 days of valganciclovir prophylaxis following anti-thymocyte globulin

or

- ○ Patient has received pulse methylprednisolone for acute rejection and requires further valganciclovir therapy for CMV prophylaxis
- **and**
- ○ Patient is to receive a maximum of 90 days of valganciclovir prophylaxis following pulse methylprednisolone

INITIATION – Lung transplant cytomegalovirus prophylaxis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has undergone a lung transplant

and

- ○ The donor was cytomegalovirus positive and the patient is cytomegalovirus negative
- **or**
- ○ The recipient is cytomegalovirus positive

and

- ○ Patient has a high risk of CMV disease

INITIATION – Cytomegalovirus in immunocompromised patients
Prerequisites (tick boxes where appropriate)

- ○ Patient is immunocompromised

and

- ○ Patient has cytomegalovirus syndrome or tissue invasive disease
- **or**
- ○ Patient has rapidly rising plasma CMV DNA in absence of disease
- **or**
- ○ Patient has cytomegalovirus retinitis

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Emtricitabine with tenofovir disoproxil

INITIATION – Confirmed HIV
Prerequisites (tick box where appropriate)

- ○ Patient has confirmed HIV infection

INITIATION – Prevention of maternal transmission
Prerequisites (tick boxes where appropriate)

- ○ Prevention of maternal foetal transmission

or

- ○ Treatment of the newborn for up to eight weeks

INITIATION – Post-exposure prophylaxis following non-occupational exposure to HIV
Prerequisites (tick boxes where appropriate)

- ○ Treatment course to be initiated within 72 hours post exposure

and

- ○ Patient has had unprotected receptive anal intercourse with a known HIV positive person

or

- ○ Patient has shared intravenous injecting equipment with a known HIV positive person

or

- ○ Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required

INITIATION – Percutaneous exposure
Prerequisites (tick box where appropriate)

- ○ Patient has percutaneous exposure to blood known to be HIV positive

INITIATION – Pre-exposure prophylaxis
Re-assessment required after 24 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has tested HIV negative, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion

and

- ○ The Practitioner considers the patient is at elevated risk of HIV exposure and use of PrEP is clinically appropriate

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines (https://ashm.org.au/HIV/Pr

CONTINUATION – Pre-exposure prophylaxis
Re-assessment required after 24 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has tested HIV negative, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion

and

- ○ The Practitioner considers the patient is at elevated risk of HIV exposure and use of PrEP is clinically appropriate

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines (https://ashm.org.au/HIV/Pr

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Oseltamivir

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Only for hospitalised patient with known or suspected influenza

or

- ○ For prophylaxis of influenza in hospitalised patients as part of a Health NZ Hospital approved infections control plan

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Zanamivir - Powder for inhalation 5 mg

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Only for hospitalised patient with known or suspected influenza

or

- ○ For prophylaxis of influenza in hospitalised patients as part of a Health NZ Hospital approved infections control plan

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

COVID-19 treatments

INITIATION

Prerequisites (tick box where appropriate)

- ○ Only if patient meets access criteria (as per https://pharmac.govt.nz/covid-oral-antivirals). Note the supply of treatment is via Pharmac's approved distribution process. Refer to the Pharmac website for more information about this and stock availability

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Remdesivir

INITIATION – Treatment of mild to moderate COVID-19

Prerequisites (tick box where appropriate)

- ○ Only if patient meets access criteria (as per https://pharmac.govt.nz/covid-oral-antivirals). Note the supply of treatment is via Pharmac's approved distribution process. Refer to the Pharmac website for more information about this and stock availability

INITIATION – COVID-19 in hospitalised patients

Re-assessment required after 5 doses

Prerequisites (tick boxes where appropriate)

- ○ Patient is hospitalised with confirmed (or probable) symptomatic COVID-19

and

- ○ Patient is considered to be at high risk of progression to severe disease

and

- ○ Patient's symptoms started within the last 7 days

and

- ○ Patient does not require, or is not expected to require, mechanical ventilation

and

- ○ Not to be used in conjunction with other funded COVID-19 antiviral treatments

and

- ○ Treatment not to exceed five days

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Interferon gamma

INITIATION

Prerequisites (tick box where appropriate)

- ○ Patient has chronic granulomatous disease and requires interferon gamma

I confirm that the above details are correct:

Signed: ..... Date: .....

RS1827 - Pegylated interferon alfa-2a

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pegylated interferon alfa-2a

INITIATION – Chronic hepatitis C - genotype 1, 4, 5 or 6 infection or co-infection with HIV or genotype 2 or 3 post liver transplant
Re-assessment required after 48 weeks
Prerequisites (tick boxes where appropriate)

- ○ Patient has chronic hepatitis C, genotype 1, 4, 5 or 6 infection

or

- ○ Patient has chronic hepatitis C and is co-infected with HIV

or

- ○ Patient has chronic hepatitis C genotype 2 or 3 and has received a liver transplant

Note: Consider stopping treatment if there is absence of a virological response (defined as at least a 2-log reduction in viral load) following 12 weeks of treatment since this is predictive of treatment failure.
Consider reducing treatment to 24 weeks if serum HCV RNA level at Week 4 is undetectable by sensitive PCR assay (less than 50IU/ml) AND Baseline serum HCV RNA is less than 400,000IU/ml.

CONTINUATION – Chronic hepatitis C - genotype 1 infection
Re-assessment required after 48 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a gastroenterologist, infectious disease specialist or general physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has chronic hepatitis C, genotype 1

and

- ○ Patient has had previous treatment with pegylated interferon and ribavirin

and

- ○ Patient has responder relapsed

or

- ○ Patient was a partial responder

and

- ○ Patient is to be treated in combination with boceprevir

INITIATION – Chronic Hepatitis C - genotype 1 infection treatment more than 4 years prior
Re-assessment required after 48 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a gastroenterologist, infectious disease specialist or general physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has chronic hepatitis C, genotype 1

and

- ○ Patient has had previous treatment with pegylated interferon and ribavirin

and

- ○ Patient has responder relapsed

or

- ○ Patient was a partial responder

or

- ○ Patient received interferon treatment prior to 2004

and

- ○ Patient is to be treated in combination with boceprevir

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pegylated interferon alfa-2a *- continued*

INITIATION – Chronic hepatitis C - genotype 2 or 3 infection without co-infection with HIV
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ Patient has chronic hepatitis C, genotype 2 or 3 infection

INITIATION – Hepatitis B
Re-assessment required after 48 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a gastroenterologist, infectious disease specialist or general physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months)

and

- ○ Patient is Hepatitis B treatment-naive

and

- ○ ALT > 2 times Upper Limit of Normal

and

- ○ HBV DNA < 10 log10 IU/ml

and

- ○ HBeAg positive

or

- ○ Serum HBV DNA greater than or equal to 2,000 units/ml and significant fibrosis (greater than or equal to Metavir Stage F2 or moderate fibrosis)

and

- ○ Compensated liver disease

and

- ○ No continuing alcohol abuse or intravenous drug use

and

- ○ Not co-infected with HCV, HIV or HDV

and

- ○ Neither ALT nor AST > 10 times upper limit of normal

and

- ○ No history of hypersensitivity or contraindications to pegylated interferon

INITIATION – myeloproliferative disorder or cutaneous T cell lymphoma
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has a cutaneous T cell lymphoma*

or

- ○ Patient has a myeloproliferative disorder*

and

- ○ Patient is intolerant of hydroxyurea

and

- ○ Treatment with anagrelide and busulfan is not clinically appropriate

or

- ○ Patient has a myeloproliferative disorder

and

- ○ Patient is pregnant, planning pregnancy or lactating

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pegylated interferon alfa-2a *- continued*

CONTINUATION – myeloproliferative disorder or cutaneous T cell lymphoma
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ No evidence of disease progression

and

- ○ The treatment remains appropriate and patient is benefitting from treatment

and

- ○ Patient has a cutaneous T cell lymphoma*

or

- ○ Patient has a myeloproliferative disorder*

and

- ○ Remains intolerant of hydroxyurea and treatment with anagrelide and busulfan remains clinically inappropriate

or

- ○ Patient is pregnant, planning pregnancy or lactating

Note: Indications marked with * are unapproved indications

INITIATION – ocular surface squamous neoplasia
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by an ophthalmologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has ocular surface squamous neoplasia*

CONTINUATION – ocular surface squamous neoplasia
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by an ophthalmologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The treatment remains appropriate and patient is benefitting from treatment

Note: Indications marked with * are unapproved indications

INITIATION – post-allogenic bone marrow transplant
Re-assessment required after 3 months
Prerequisites (tick box where appropriate)

- ○ Patient has received an allogeneic bone marrow transplant* and has evidence of disease relapse

CONTINUATION – post-allogenic bone marrow transplant
Re-assessment required after 3 months
Prerequisites (tick box where appropriate)

- ○ Patient is responding and ongoing treatment remains appropriate

Note: Indications marked with * are unapproved indications

I confirm that the above details are correct:

Signed: ..... Date: .....

Musculoskeletal System

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Edrophonium chloride

INITIATION

Prerequisites (tick box where appropriate)

- ○ For the diagnosis of myasthenia gravis

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Denosumab

INITIATION – Osteoporosis

Prerequisites (tick boxes where appropriate)

- ○ The patient has established osteoporosis

and

- ○ History of one significant osteoporotic fracture demonstrated radiologically, with a documented T-Score less than or equal to -2.5, that incorporates BMD measured using dual-energy x-ray absorptiometry (DEXA)

or

- ○ History of one significant osteoporotic fracture, demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of logistical, technical or pathophysiological reasons

or

- ○ History of two significant osteoporotic fractures demonstrated radiologically

or

- ○ Documented T-Score less than or equal to -3.0

or

- ○ A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm that incorporates BMD measured using DEXA

and

- ○ Bisphosphonates are contraindicated because the patient's creatinine clearance or eGFR is less than 35 mL/min

or

- ○ The patient has experienced at least two symptomatic new fractures or a BMD loss greater than 2% per year, after at least 12 months' continuous therapy with a funded antiresorptive agent

or

- ○ Bisphosphonates result in intolerable side effects

or

- ○ Intravenous bisphosphonates cannot be administered due to logistical or technical reasons

INITIATION – Hypercalcaemia

Prerequisites (tick boxes where appropriate)

- ○ Patient has hypercalcaemia of malignancy

and

- ○ Patient has severe renal impairment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Raloxifene

INITIATION

Prerequisites (tick boxes where appropriate)

- ❍ History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Notes)

or

- ❍ History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age

or

- ❍ History of two significant osteoporotic fractures demonstrated radiologically

or

- ❍ Documented T-Score greater than or equal to -3.0 (see Notes)

or

- ❍ A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Notes)

or

- ❍ Patient has had a Special Authority approval for zoledronic acid (Underlying cause - Osteoporosis) or has had a Special Authority approval for alendronate (Underlying cause - Osteoporosis) prior to 1 February 2019

Note:

a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.

b) Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for raloxifene funding.

c) Osteoporotic fractures are the incident events for severe (established) osteoporosis, and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.

d) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Teriparatide

INITIATION
Re-assessment required after 18 months
Prerequisites (tick boxes where appropriate)

- ❍ The patient has severe, established osteoporosis

and

- ❍ The patient has a documented T-score less than or equal to -3.0 (see Notes)

and

- ❍ The patient has had two or more fractures due to minimal trauma

and

- ❍ The patient has experienced at least one symptomatic new fracture after at least 12 months' continuous therapy with a funded antiresorptive agent at adequate doses (see Notes)

Note:

a) The bone mineral density (BMD) measurement used to derive the T-score must be made using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable

b) Antiresorptive agents and their adequate doses for the purposes of this restriction are defined as: alendronate sodium tab 70 mg or tab 70 mg with colecalciferol 5,600 iu once weekly; raloxifene hydrochloride tab 60 mg once daily; zoledronic acid 5 mg per year. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the use of one antiresorptive agent, an alternate antiresorptive agent must be trialled so that the patient achieves the minimum requirement of 12 months' continuous therapy.

c) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rasburicase

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Febuxostat

INITIATION – Gout

Prerequisites (tick boxes where appropriate)

- ○ Patient has been diagnosed with gout

and

- ○ The patient has a serum urate level greater than 0.36 mmol/l despite treatment with allopurinol at doses of at least 600 mg/day and addition of probenecid at doses of up to 2 g per day or maximum tolerated dose

or

- ○ The patient has experienced intolerable side effects from allopurinol such that treatment discontinuation is required and serum urate remains greater than 0.36 mmol/l despite use of probenecid at doses of up to 2 g per day or maximum tolerated dose

or

- ○ The patient has renal impairment such that probenecid is contraindicated or likely to be ineffective and serum urate remains greater than 0.36 mmol/l despite optimal treatment with allopurinol (see Note)

or

- ○ The patient has previously had an initial Special Authority approval for benzbromarone for treatment of gout.

INITIATION – Tumour lysis syndrome

Re-assessment required after 6 weeks

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist or oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is scheduled to receive cancer therapy carrying an intermediate or high risk of tumour lysis syndrome

and

- ○ Patient has a documented history of allopurinol intolerance

CONTINUATION – Tumour lysis syndrome

Re-assessment required after 6 weeks

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a haematologist or oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The treatment remains appropriate and patient is benefitting from treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sugammadex

INITIATION

Prerequisites (tick boxes where appropriate)

- ❍ Patient requires reversal of profound neuromuscular blockade following rapid sequence induction that has been undertaken using rocuronium (i.e. suxamethonium is contraindicated or undesirable)

or

- ❍ Severe neuromuscular degenerative disease where the use of neuromuscular blockade is required

or

- ❍ Patient has an unexpectedly difficult airway that cannot be intubated and requires a rapid reversal of anaesthesia and neuromuscular blockade

or

- ❍ The duration of the patient's surgery is unexpectedly short

or

- ❍ Neostigmine or a neostigmine/anticholinergic combination is contraindicated (for example the patient has ischaemic heart disease, morbid obesity or COPD)

or

- ❍ Patient has a partial residual block after conventional reversal

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etoricoxib

INITIATION

Prerequisites (tick box where appropriate)

○ For in-vivo investigation of allergy only

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Capsaicin

INITIATION

Prerequisites (tick box where appropriate)

- ○ Patient has osteoarthritis that is not responsive to paracetamol and oral non-steroidal anti-inflammatories are contraindicated

I confirm that the above details are correct:

Signed: ..... Date: .....

Nervous System

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Riluzole

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a neurologist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has amyotrophic lateral sclerosis with disease duration of 5 years or less

and

- ○ The patient has at least 60 percent of predicted forced vital capacity within 2 months prior to the initial application

and

- ○ The patient has not undergone a tracheostomy

and

- ○ The patient has not experienced respiratory failure

and

- ○ The patient is ambulatory

or

- ○ The patient is able to use upper limbs

or

- ○ The patient is able to swallow

CONTINUATION
Re-assessment required after 18 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has not undergone a tracheostomy

and

- ○ The patient has not experienced respiratory failure

and

- ○ The patient is ambulatory

or

- ○ The patient is able to use upper limbs

or

- ○ The patient is able to swallow

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sucrose

INITIATION

Prerequisites (tick box where appropriate)

○ For use in neonatal patients only

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Methoxyflurane

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient is undergoing a painful procedure with an expected duration of less than one hour

and

- ○ Only to be used under supervision by a medical practitioner or nurse who is trained in the use of methoxyflurane

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Paracetamol

INITIATION

Prerequisites (tick box where appropriate)

- ○ Intravenous paracetamol is only to be used where other routes are unavailable or impractical, or where there is reduced absorption. The need for IV paracetamol must be re-assessed every 24 hours

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Capsaicin

INITIATION

Prerequisites (tick box where appropriate)

- ○ For post-herpetic neuralgia or diabetic peripheral neuropathy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Vigabatrin

INITIATION
Re-assessment required after 15 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has infantile spasms
- **or**
- ○ Patient has epilepsy
- **and**
- ○ Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents
- **or**
- ○ Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents
- **or**
- ○ Patient has tuberous sclerosis complex
- **and**
- ○ Patient is, or will be, receiving regular automated visual field testing (ideally before starting therapy and on a 6-monthly basis thereafter)
- **or**
- ○ It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields

CONTINUATION
Prerequisites (tick boxes where appropriate)

- ○ The patient has demonstrated a significant and sustained improvement in seizure rate or severity and or quality of life
- **and**
- ○ Patient is receiving regular automated visual field testing (ideally every 6 months) on an ongoing basis for duration of treatment with vigabatrin
- **or**
- ○ It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Lacosamide

INITIATION
Re-assessment required after 15 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has focal epilepsy

and

- ○ Seizures are not adequately controlled by, or patient has experienced unacceptable side effects from, optimal treatment with all of the following: sodium valproate, topiramate, levetiracetam, and any two of carbamazepine, lamotrigine, and phenytoin sodium (see Note)

Note: Those of childbearing potential are not required to trial phenytoin sodium, sodium valproate, or topiramate. Those who can father children are not required to trial sodium valproate.

CONTINUATION
Prerequisites (tick box where appropriate)

- ○ Patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life compared with that prior to starting lacosamide treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Stiripentol

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a paediatric neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has confirmed diagnosis of Dravet syndrome

and

- ○ Seizures have been inadequately controlled by appropriate courses of sodium valproate, clobazam and at least two of the following: topiramate, levetiracetam, ketogenic diet

Note: Those of childbearing potential are not required to trial sodium valproate or topiramate. Those who can father children are not required to trial sodium valproate.

CONTINUATION
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a paediatric neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient continues to benefit from treatment as measured by reduced seizure frequency from baseline

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Hyoscine hydrobromide - Patch 1.5 mg

INITIATION

Prerequisites (tick boxes where appropriate)

- ❍ Control of intractable nausea, vomiting, or inability to swallow saliva in the treatment of malignancy or chronic disease where the patient cannot tolerate or does not adequately respond to oral anti-nausea agents

or

- ❍ Control of clozapine-induced hypersalivation where trials of at least two other alternative treatments have proven ineffective

or

- ❍ For treatment of post-operative nausea and vomiting where cyclizine, droperidol and a 5HT3 antagonist have proven ineffective, are not tolerated or are contraindicated

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Aprepitant

INITIATION

Prerequisites (tick box where appropriate)

- ○ Patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Paliperidone

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has had an initial Special Authority approval for risperidone depot injection or olanzapine depot injection or aripiprazole depot injection

or

- ○ The patient has schizophrenia or other psychotic disorder

and

- ○ The patient has been unable to adhere to treatment using oral atypical antipsychotic agents

and

- ○ The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in the last 12 months

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ The initiation of paliperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Paliperidone palmitate

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has schizophrenia

and

- ○ The patient has had an initial Special Authority approval for paliperidone once-monthly depot injection

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ The initiation of paliperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Olanzapine

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ The initiation of olanzapine depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Risperidone

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has had an initial Special Authority approval for paliperidone depot injection or olanzapine depot injection or aripiprazole depot injection

or

- ○ The patient has schizophrenia or other psychotic disorder

and

- ○ The patient has not been able to adhere to treatment using oral atypical antipsychotic agents

and

- ○ The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in the last 12 months

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ The initiation of risperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Aripiprazole

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ The patient has had an initial Special Authority approval for risperidone depot injection or paliperidone depot injection or olanzapine depot injection

or

- ○ The patient has schizophrenia or other psychotic disorder

and

- ○ The patient has received treatment with oral atypical antipsychotic agents but has been unable to adhere

and

- ○ The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in last 12 months

or

- ○ Patient has been unable to access olanzapine depot injection due to supply issues with olanzapine depot injection, or otherwise would have been initiated on olanzapine depot injection but has been unable to due to supply issues with olanzapine depot injection. (see Note below for the olanzapine Special Authority criteria for new olanzapine depot injection patients prior to 1 April 2024)

Note: The Olanzapine depot injection Special Authority criteria that apply to criterion 2 in this Aripiprazole Special Authority application are as follows:

- The patient has had an initial Special Authority approval for paliperidone depot injection or risperidone depot injection; or
- All of the following:
  - The patient has schizophrenia; and
  - The patient has tried but has not been able to adhere with treatment using oral atypical antipsychotic agents; and
  - The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in the last 12 months.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Diazepam

INITIATION

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Only for use in children where diazepam tablets are not appropriate

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Multiple Sclerosis

INITIATION – Multiple Sclerosis - dimethyl fumarate, fingolimod, glatiramer acetate, interferon beta-1-alpha, interferon beta-1-beta, natalizumab and teriflunomide
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Diagnosis of multiple sclerosis (MS) meets the McDonald 2017 diagnostic criteria for MS and has been confirmed by a neurologist

and

- ○ Patient has an EDSS score between 0 – 6.0

and

- ○ Patient has had at least one significant attack of MS in the previous 12 months or two significant attacks in the past 24 months

and

- ○ Each significant attack must be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the attack, but the neurologist/physician must be satisfied that the clinical features were characteristic)

and

- ○ Each significant attack is associated with characteristic new symptom(s)/sign(s) or substantially worsening of previously experienced symptoms(s)/sign(s)

and

- ○ Each significant attack has lasted at least one week and has started at least one month after the onset of a previous attack (where relevant)

and

- ○ Each significant attack can be distinguished from the effects of general fatigue; and is not associated with a fever (T> 37.5°C)

and

- ○ Each significant attack is severe enough to change either the EDSS or at least one of the Kurtze Functional System scores by at least 1 point

or

- ○ Each significant attack is a recurrent paroxysmal symptom of multiple sclerosis (tonic seizures/spasms, trigeminal neuralgia, Lhermitte's symptom)

and

- ○ Evidence of new inflammatory activity on an MRI scan within the past 24 months

and

- ○ A sign of that new inflammatory activity on MRI scanning (in criterion 5 immediately above) is a gadolinium enhancing lesion

or

- ○ A sign of that new inflammatory activity is a lesion showing diffusion restriction

or

- ○ A sign of that new inflammatory is a T2 lesion with associated local swelling

or

- ○ A sign of that new inflammatory activity is a prominent T2 lesion that clearly is responsible for the clinical features of a recent attack that occurred within the last 2 years

or

- ○ A sign of that new inflammatory activity is new T2 lesions compared with a previous MRI scan

or

- ○ Patient has an active approval for ocrelizumab and does not have primary progressive MS

Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Multiple Sclerosis *- continued*

CONTINUATION – Multiple Sclerosis - dimethyl fumarate, fingolimod, glatiramer acetate, interferon beta-1-alpha, interferon beta-1-beta, natalizumab and teriflunomide

Prerequisites (tick box where appropriate)

❍ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ Patient has had an EDSS score of 0 to 6.0 (inclusive) with or without the use unilateral or bilateral aids at any time in the last six months (ie the patient has walked 100 metres or more with or without aids in the last six months)

Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Multiple Sclerosis

INITIATION – Multiple Sclerosis - ocrelizumab
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Diagnosis of multiple sclerosis (MS) meets the McDonald 2017 diagnostic criteria for MS and has been confirmed by a neurologist

and

- ○ Patient has an EDSS score between 0 – 6.0

and

- ○ Patient has had at least one significant attack of MS in the previous 12 months or two significant attacks in the past 24 months

and

- ○ Each significant attack must be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the attack, but the neurologist/physician must be satisfied that the clinical features were characteristic)

and

- ○ Each significant attack is associated with characteristic new symptom(s)/sign(s) or substantially worsening of previously experienced symptoms(s)/sign(s)

and

- ○ Each significant attack has lasted at least one week and has started at least one month after the onset of a previous attack (where relevant)

and

- ○ Each significant attack can be distinguished from the effects of general fatigue; and is not associated with a fever (T> 37.5°C)

and

- ○ Each significant attack is severe enough to change either the EDSS or at least one of the Kurtze Functional System scores by at least 1 point

or

- ○ Each significant attack is a recurrent paroxysmal symptom of multiple sclerosis (tonic seizures/spasms, trigeminal neuralgia, Lhermitte's symptom)

and

- ○ Evidence of new inflammatory activity on an MRI scan within the past 24 months

and

- ○ A sign of that new inflammatory activity on MRI scanning (in criterion 5 immediately above) is a gadolinium enhancing lesion

or

- ○ A sign of that new inflammatory activity is a lesion showing diffusion restriction

or

- ○ A sign of that new inflammatory is a T2 lesion with associated local swelling

or

- ○ A sign of that new inflammatory activity is a prominent T2 lesion that clearly is responsible for the clinical features of a recent attack that occurred within the last 2 years

or

- ○ A sign of that new inflammatory activity is new T2 lesions compared with a previous MRI scan

or

- ○ Patient has an active Special Authority approval for either dimethyl fumarate, fingolimod, glatiramer acetate, interferon beta-1-alpha, interferon beta-1-beta, natalizumab or teriflunomide

Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Multiple Sclerosis *- continued*

CONTINUATION – Multiple Sclerosis - ocrelizumab

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has had an EDSS score of 0 to 6.0 (inclusive) with or without the use unilateral or bilateral aids at any time in the last six months (ie the patient has walked 100 metres or more with or without aids in the last six months)

Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

INITIATION – Primary Progressive Multiple Sclerosis

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Diagnosis of primary progressive multiple sclerosis (PPMS) meets the 2017 McDonald criteria and has been confirmed by a neurologist

and

- ○ Patient has an EDSS 2.0 (score equal to or greater than 2 on pyramidal functions) to EDSS 6.5

and

- ○ Patient has no history of relapsing remitting multiple sclerosis

CONTINUATION – Primary Progressive Multiple Sclerosis

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has had an EDSS score of less than or equal to 6.5 at any time in the last six months (ie patient has walked 20 metres with bilateral assistance/aids, without rest in the last six months)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Melatonin

INITIATION – insomnia secondary to neurodevelopmental disorder
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a psychiatrist, paediatrician, neurologist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has been diagnosed with persistent and distressing insomnia secondary to a neurodevelopmental disorder (including, but not limited to, autism spectrum disorder or attention deficit hyperactivity disorder)

and

- ○ Behavioural and environmental approaches have been tried or are inappropriate

and

- ○ Funded modified-release melatonin is to be given at doses no greater than 10 mg per day

and

- ○ Patient is aged 18 years or under

CONTINUATION – insomnia secondary to neurodevelopmental disorder
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a psychiatrist, paediatrician, neurologist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is aged 18 years or under

and

- ○ Patient has demonstrated clinically meaningful benefit from funded modified-release melatonin (clinician determined)

and

- ○ Patient has had a trial of funded modified-release melatonin discontinuation within the past 12 months and has had a recurrence of persistent and distressing insomnia

and

- ○ Funded modified-release melatonin is to be given at doses no greater than 10 mg per day

INITIATION – insomnia where benzodiazepines and zopiclone are contraindicated
Prerequisites (tick boxes where appropriate)

- ○ Patient has insomnia and benzodiazepines and zopiclone are contraindicated

and

- ○ For in-hospital use only

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nusinersen

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has genetic documentation of homozygous SMN1 gene deletion, homozygous SMN1 point mutation, or compound heterozygous mutation

and

- ○ Patient is 18 years of age or under

and

- ○ Patient has experienced the defined signs and symptoms of SMA type I, II or IIIa prior to three years of age

or

- ○ Patient is pre-symptomatic

and

- ○ Patient has three or less copies of SMN2

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ There has been demonstrated maintenance of motor milestone function since treatment initiation

and

- ○ Patient does not require invasive permanent ventilation (at least 16 hours per day), in the absence of a potentially reversible cause while being treated with nusinersen

and

- ○ Nusinersen not to be administered in combination other SMA disease modifying treatments or gene therapy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Risdiplam

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has genetic documentation of homozygous SMN1 gene deletion, homozygous SMN1 point mutation, or compound heterozygous mutation

and

- ○ Patient is 18 years of age or under

and

- ○ Patient has experienced the defined signs and symptoms of SMA type I, II or IIIa prior to three years of age

or

- ○ Patient is pre-symptomatic

and

- ○ Patient has three or less copies of SMN2

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ There has been demonstrated maintenance of motor milestone function since treatment initiation

and

- ○ Patient does not require invasive permanent ventilation (at least 16 hours per day), in the absence of a potentially reversible cause while being treated with risdiplam

and

- ○ Risdiplam not to be administered in combination other SMA disease modifying treatments or gene therapy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Modafinil

INITIATION – Narcolepsy

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a neurologist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ The patient has a diagnosis of narcolepsy and has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more

and

❍ The patient has a multiple sleep latency test with a mean sleep latency of less than or equal to 10 minutes and 2 or more sleep onset rapid eye movement periods

or

❍ The patient has at least one of: cataplexy, sleep paralysis or hypnagogic hallucinations

and

❍ An effective dose of a listed formulation of methylphenidate or dexamphetamine has been trialled and discontinued because of intolerable side effects

or

❍ Methylphenidate and dexamphetamine are contraindicated

or

❍ Patient meets the Hospital Restriction criteria for methylphenidate hydrochloride for narcolepsy

and

❍ Patient is unable to access methylphenidate hydrochloride presentations due to an out of stock (see note)

Note: Criterion 2 is to permit short-term funding to cover an out-of-stock of methylphenidate hydrochloride.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Lisdexamfetamine dimesilate

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a paediatrician or psychiatrist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is currently on treatment with lisdexamfetamine dimesilate and met all remaining criteria prior to commencing treatment

or

- ○ ADHD (Attention Deficit and Hyperactivity Disorder)

and

- ○ Diagnosed according to DSM-V or ICD 11 criteria

and

- ○ Patient is taking a currently subsidised formulation of atomoxetine or methylphenidate hydrochloride (extended-release) and has not received sufficient benefit or has experienced intolerable side effects

or

- ○ Patient is taking a currently subsidised formulation of dexamfetamine sulfate (immediate-release) which has not been effective due to significant administration and/or treatment adherence difficulties

or

- ○ There is significant concern regarding the risk of diversion or abuse of immediate release dexamfetamine sulfate

or

- ○ Patient is taking a currently subsidised formulation of methylphenidate hydrochloride (immediate-release or sustained release) which has not been effective due to significant administration and/or treatment adherence difficulties

or

- ○ There is significant concern regarding the risk of diversion or abuse of immediate release methylphenidate hydrochloride

or

- ○ Patient would have been prescribed a subsidised formulation of methylphenidate hydrochloride (extended-release) but has been unable to access due to supply issues with methylphenidate hydrochloride (extended-release)

and

- ○ Other alternative stimulant presentations (methylphenidate or dexamfetamine) are not appropriate

and

- ○ Lisdexamfetamine dimesilate is not to be used in combination with another funded methylphenidate presentation

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Methylphenidate hydrochloride

INITIATION – ADHD (immediate-release and sustained-release formulations)

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a paediatrician or psychiatrist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has ADHD (Attention Deficit and Hyperactivity Disorder), diagnosed according to DSM-IV or ICD 10 criteria

INITIATION – Narcolepsy (immediate-release and sustained-release formulations)

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a neurologist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient suffers from narcolepsy

INITIATION – Extended-release and modified-release formulations

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a paediatrician or psychiatrist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has ADHD (Attention Deficit and Hyperactivity Disorder), diagnosed according to DSM-IV or ICD 10 criteria

and

- ○ Patient is taking a currently listed formulation of methylphenidate hydrochloride (immediate-release or sustained-release) which has not been effective due to significant administration and/or compliance difficulties

or

- ○ There is significant concern regarding the risk of diversion or abuse of immediate-release methylphenidate hydrochloride

INITIATION – Narcolepsy* (extended-release only)

Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a neurologist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient suffers from narcolepsy

Note: *narcolepsy is not a registered indication for Concerta or Ritalin LA.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Dexamphetamine sulphate

INITIATION – ADHD

Prerequisites (tick box where appropriate)

- ❍ Prescribed by, or recommended by a paediatrician or psychiatrist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ Patient has ADHD (Attention Deficit and Hyperactivity Disorder), diagnosed according to DSM-IV or ICD 10 criteria

INITIATION – Narcolepsy

Prerequisites (tick box where appropriate)

- ❍ Prescribed by, or recommended by a neurologist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ Patient suffers from narcolepsy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rivastigmine

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has been diagnosed with dementia

and

- ○ The patient has experienced intolerable nausea and/or vomiting from donepezil tablets

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The treatment remains appropriate

and

- ○ The patient has demonstrated a significant and sustained benefit from treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Naltrexone hydrochloride

INITIATION – Alcohol dependence

Prerequisites (tick boxes where appropriate)

- ○ Patient is currently enrolled, or is planned to be enrolled, in a recognised comprehensive treatment programme for alcohol dependence

and

- ○ Naltrexone is to be prescribed by, or on the recommendation of, a physician working in an Alcohol and Drug Service

INITIATION – Constipation

Prerequisites (tick box where appropriate)

- ○ For the treatment of opioid-induced constipation

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nicotine

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For perioperative use in patients who have a 'nil by mouth' instruction

or

- ○ For use within mental health inpatient units

or

- ○ Patient would be admitted to a mental health inpatient unit, but is unable to due to COVID-19 self-isolation requirement

or

- ○ For acute use in agitated patients who are unable to leave the hospital facilities

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Varenicline

INITIATION

Prerequisites (tick boxes where appropriate)

- ❍ Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking

and

- ❍ The patient is part of, or is about to enrol in, a comprehensive support and counselling smoking cessation programme, which includes prescriber or nurse monitoring

and

- ❍ The patient has tried but failed to quit smoking after at least two separate trials of nicotine replacement therapy, at least one of which included the patient receiving comprehensive advice on the optimal use of nicotine replacement therapy

or

- ❍ The patient has tried but failed to quit smoking using bupropion or nortriptyline

and

- ❍ The patient has not had a Special Authority for varenicline approved in the last 6 months

and

- ❍ Varenicline is not to be used in combination with other pharmacological smoking cessation treatments and the patient has agreed to this

and

- ❍ The patient is not pregnant

and

- ❍ The patient will not be prescribed more than 12 weeks' funded varenicline in a 12 month period

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Buprenorphine with naloxone

INITIATION – Detoxification

Prerequisites (tick boxes where appropriate)

- ○ Patient is opioid dependent

and

- ○ Patient is currently engaged with an opioid treatment service approved by the Ministry of Health

and

- ○ Prescriber works in an opioid treatment service approved by the Ministry of Health

INITIATION – Maintenance treatment

Prerequisites (tick boxes where appropriate)

- ○ Patient is opioid dependent

and

- ○ Patient will not be receiving methadone

and

- ○ Patient is currently enrolled in an opioid substitution treatment program in a service approved by the Ministry of Health

and

- ○ Prescriber works in an opioid treatment service approved by the Ministry of Health

I confirm that the above details are correct:

Signed: ..... Date: .....

Oncology Agents and Immunosuppressants

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Bendamustine hydrochloride

INITIATION – CLL*

Prerequisites (tick boxes where appropriate)

- ○ The patient has chronic lymphocytic leukaemia requiring treatment

and

- ○ Patient has ECOG performance status 0-2

and

- ○ Bendamustine is to be administered at a maximum dose of 100 mg/m^2 on days 1 and 2 every 4 weeks for a maximum of 6 cycles

Note: Indication marked with a * includes indications that are unapproved. 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL).

INITIATION – Indolent, Low-grade lymphomas

Re-assessment required after 9 months

Prerequisites (tick boxes where appropriate)

- ○ The patient has indolent low grade NHL requiring treatment

and

- ○ Patient has ECOG performance status of 0-2

and

- ○ Patient is treatment naive

  and

  ○ Bendamustine is to be administered for a maximum of 6 cycles (in combination with rituximab when CD20+)

or

- ○ Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemo-immunotherapy regimen

  and

  ○ Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles

or

- ○ The patient has not received prior bendamustine therapy

  and

  ○ Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+)

  and

  ○ Patient has had a rituximab treatment-free interval of 12 months or more

or

- ○ Bendamustine is to be administered as monotherapy for a maximum of 6 cycles in rituximab refractory patients

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Bendamustine hydrochloride *- continued*

CONTINUATION – Indolent, Low-grade lymphomas
Re-assessment required after 9 months
Prerequisites (tick boxes where appropriate)

- ○ Patient is refractory to or has relapsed within 12 months of rituximab in combination with bendamustine
- **and**
- ○ Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles

or

- ○ Patients have not received a bendamustine regimen within the last 12 months
- **and**
  - ○ Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+)
  - **and**
  - ○ Patient has had a rituximab treatment-free interval of 12 months or more
  - **or**
  - ○ Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients

Note: 'indolent, low-grade lymphomas' includes follicular, mantle cell, marginal zone and lymphoplasmacytic/ Waldenström's macroglobulinaemia.

INITIATION – Hodgkin's lymphoma*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has Hodgkin's lymphoma requiring treatment
- **and**
- ○ Patient has a ECOG performance status of 0-2
- **and**
- ○ Patient has received one prior line of chemotherapy
- **and**
- ○ Patient's disease relapsed or was refractory following prior chemotherapy
- **and**
- ○ Bendamustine is to be administered in combination with gemcitabine and vinorelbine (BeGeV) at a maximum dose of no greater than 90 mg/m2 twice per cycle, for a maximum of four cycles

Note: Indications marked with * are unapproved indications.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Azacitidine

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The individual has intermediate or high risk MDS based on an internationally recognised scoring system

or

- ○ The individual has chronic myelomonocytic leukaemia (based on an intermediate or high risk score from an internationally recognised scoring system or 10%-29% marrow blasts without myeloproliferative disorder)

or

- ○ The individual has acute myeloid leukaemia according to World Health Organisation (WHO) Classification

and

- ○ The individual has an estimated life expectancy of at least 3 months

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ No evidence of disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Mercaptopurine

INITIATION
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a paediatric haematologist or paediatric oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient requires a total dose of less than one full 50 mg tablet per day

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a paediatric haematologist or paediatric oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient requires a total dose of less than one full 50 mg tablet per day

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Venetoclax

INITIATION – relapsed/refractory chronic lymphocytic leukaemia
Re-assessment required after 7 months
Prerequisites (tick boxes where appropriate)

- ○ Individual has chronic lymphocytic leukaemia requiring treatment

and

- ○ Individual has received at least one prior therapy for chronic lymphocytic leukaemia

and

- ○ Individual has not previously received funded venetoclax

and

- ○ The individual's disease has relapsed

and

- ○ Venetoclax to be used in combination with six 28-day cycles of rituximab commencing after the 5-week dose titration schedule with venetoclax

and

- ○ Individual has an ECOG performance status of 0-2

CONTINUATION – relapsed/refractory chronic lymphocytic leukaemia
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Treatment remains clinically appropriate and the individual is benefitting from and tolerating treatment

and

- ○ Venetoclax is to be discontinued after a maximum of 24 months of treatment following the titration schedule unless earlier discontinuation is required due to disease progression or unacceptable toxicity

INITIATION – previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Individual has previously untreated chronic lymphocytic leukaemia

and

- ○ There is documentation confirming that the individual has 17p deletion by FISH testing or TP53 mutation by sequencing

and

- ○ Individual has an ECOG performance status of 0-2

CONTINUATION – previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ No evidence of disease progression

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL)* and B-cell prolymphocytic leukaemia (B-PLL)*. Indications marked with * are unapproved indications

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Venetoclax *- continued*

INITIATION – previously untreated acute myeloid leukaemia
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

❍ The individual is currently on treatment with venetoclax and met all remaining special authority criteria prior to commencing treatment

or

❍ Individual has previously untreated acute myeloid leukaemia (see note a), according to World Health Organization (WHO) Classification

and

❍ Venetoclax not to be used in combination with standard intensive remission induction chemotherapy

and

❍ Venetoclax to be used in combination with azacitidine or low dose cytarabine

CONTINUATION – previously untreated acute myeloid leukaemia
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

❍ No evidence of disease progression

Note:

a) 'Acute myeloid leukaemia' includes myeloid sarcoma*

b) Indications marked with * are Unapproved indications

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Olaparib

INITIATION – Ovarian cancer
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has a high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer

and

- ○ There is documentation confirming pathogenic germline BRCA1 or BRCA2 gene mutation

and

- ○ Patient has newly diagnosed, advanced disease

  and

  ○ Patient has received one line** of previous treatment with platinum-based chemotherapy

  and

  ○ Patient's disease must have experienced a partial or complete response to the first-line platinum-based regimen

or

- ○ Patient has received at least two lines** of previous treatment with platinum-based chemotherapy

  and

  ○ Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line** of platinum-based chemotherapy

  and

  ○ Patient's disease must have experienced a partial or complete response to treatment with the immediately preceding platinum-based regimen

  and

  ○ Patient has not previously received funded olaparib treatment

and

- ○ Treatment will be commenced within 12 weeks of the patient's last dose of the immediately preceding platinum-based regimen

and

- ○ Treatment to be administered as maintenance treatment

and

- ○ Treatment not to be administered in combination with other chemotherapy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Olaparib *- continued*

CONTINUATION – Ovarian cancer
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Treatment remains clinically appropriate and patient is benefitting from treatment

and

- ○ No evidence of progressive disease

or

- ○ Evidence of residual (not progressive) disease and the patient would continue to benefit from treatment in the clinician's opinion

and

- ○ Treatment to be administered as maintenance treatment

and

- ○ Treatment not to be administered in combination with other chemotherapy

and

- ○ Patient has received one line** of previous treatment with platinum-based chemotherapy

and

- ○ Documentation confirming that the patient has been informed and acknowledges that the funded treatment period of olaparib will not be continued beyond 2 years if the patient experiences a complete response to treatment and there is no radiological evidence of disease at 2 years

or

- ○ Patient has received at least two lines** of previous treatment with platinum-based chemotherapy

Note: *Note "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component.
**A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ibrutinib

INITIATION – chronic lymphocytic leukaemia (CLL)
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Individual has chronic lymphocytic leukaemia (CLL) requiring therapy

and

- ○ Individual has not previously received funded ibrutinib

and

- ○ Ibrutinib is to be used as monotherapy

and

- ○ There is documentation confirming that the individual has 17p deletion or TP53 mutation

  and

  ○ Individual has experienced intolerable side effects with venetoclax monotherapy

or

- ○ Individual has received at least one prior immunochemotherapy for CLL

  and

  ○ Individual's CLL has relapsed

  and

  ○ Individual has experienced intolerable side effects with venetoclax in combination with rituximab regimen

or

- ○ Individual's CLL is refractory to or has relapsed following a venetoclax regimen

CONTINUATION – chronic lymphocytic leukaemia (CLL)
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ No evidence of clinical disease progression

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL) and B-cell prolymphocytic leukaemia (B-PLL)*. Indications marked with * are Unapproved indications.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Niraparib

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has advanced high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer

and

- ○ Patient has received at least one line** of treatment with platinum-based chemotherapy

and

- ○ Patient has experienced a partial or complete response to the preceding treatment with platinum-based chemotherapy

and

- ○ Patient has not previously received funded treatment with a PARP inhibitor

and

- ○ Treatment will be commenced within 12 weeks of the patient's last dose of the preceding platinum-based regimen

or

- ○ Patient commenced treatment with niraparib prior to 1 May 2024

and

- ○ Treatment to be administered as maintenance treatment

and

- ○ Treatment not to be administered in combination with other chemotherapy

CONTINUATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ No evidence of progressive disease

and

- ○ Treatment to be administered as maintenance treatment

and

- ○ Treatment not to be administered in combination with other chemotherapy

and

- ○ Treatment with niraparib to cease after a total duration of 36 months from commencement

or

- ○ Treatment with niraparib is being used in the second-line or later maintenance setting

Note: * "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component.
**A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments

I confirm that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Lenalidomide

INITIATION – Plasma cell dyscrasia

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment

and

- ○ Patient is not refractory to prior lenalidomide use

INITIATION – Myelodysplastic syndrome

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has low or intermediate-1 risk myelodysplastic syndrome (based on IPSS or an IPSS-R score of less than 3.5) associated with a deletion 5q cytogenetic abnormality

and

- ○ Patient has transfusion-dependent anaemia

CONTINUATION – Myelodysplastic syndrome

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has not needed a transfusion in the last 4 months

and

- ○ No evidence of disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pomalidomide

INITIATION – Relapsed/refractory plasma cell dyscrasia
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ❍ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ Patient has relapsed or refractory plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment

and

- ❍ Patient has not received prior funded pomalidomide

CONTINUATION – Relapsed/refractory plasma cell dyscrasia
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ❍ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ Patient has no evidence of disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Temozolomide

INITIATION – gliomas
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Patient has a glioma

CONTINUATION – gliomas
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Treatment remains appropriate and patient is benefitting from treatment

INITIATION – Neuroendocrine tumours
Re-assessment required after 9 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has been diagnosed with metastatic or unresectable well-differentiated neuroendocrine tumour*

and

- ○ Temozolomide is to be given in combination with capecitabine

and

- ○ Temozolomide is to be used in 28 day treatment cycles for a maximum of 5 days treatment per cycle at a maximum dose of 200 mg/m^2 per day

and

- ○ Temozolomide to be discontinued at disease progression

CONTINUATION – Neuroendocrine tumours
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ No evidence of disease progression

and

- ○ The treatment remains appropriate and the patient is benefitting from treatment

INITIATION – ewing's sarcoma
Re-assessment required after 9 months
Prerequisites (tick box where appropriate)

- ○ Patient has relapse or refractory Ewing's sarcoma

CONTINUATION – ewing's sarcoma
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ No evidence of disease progression

and

- ○ The treatment remains appropriate and the patient is benefitting from treatment

Note: Indication marked with a * is an unapproved indication. Temozolomide is not funded for the treatment of relapsed high grade glioma.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Thalidomide

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment

or

- ○ The patient has erythema nodosum leprosum

CONTINUATION
Prerequisites (tick box where appropriate)

- ○ Patient has obtained a response from treatment during the initial approval period

Note: Prescription must be written by a registered prescriber in the thalidomide risk management programme operated by the supplier
Maximum dose of 400 mg daily as monotherapy or in a combination therapy regimen

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Bortezomib

INITIATION – plasma cell dyscrasia

Prerequisites (tick box where appropriate)

- ○ The patient has plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pegaspargase

INITIATION – Newly diagnosed ALL
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has newly diagnosed acute lymphoblastic leukaemia

and

- ○ Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol

INITIATION – Relapsed ALL
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has relapsed acute lymphoblastic leukaemia

and

- ○ Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol

INITIATION – Lymphoma
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Patient has lymphoma requiring L-asparaginase containing protocol (e.g. SMILE)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nilotinib

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis, high risk chronic phase, or in chronic phase

and

- ○ Patient has documented CML treatment failure* with a tyrosine kinase inhibitor (TKI)

or

- ○ Patient has experienced treatment limiting toxicity with a tyrosine kinase inhibitor (TKI) precluding further treatment

and

- ○ Maximum nilotinib dose of 800 mg/day

and

- ○ Subsidised for use as monotherapy only

Note: *treatment failure as defined by Leukaemia Net Guidelines.

CONTINUATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Lack of treatment failure while on nilotinib as defined by Leukaemia Net Guidelines

and

- ○ Nilotinib treatment remains appropriate and the patient is benefiting from treatment

and

- ○ Maximum nilotinib dose of 800 mg/day

and

- ○ Subsidised for use as monotherapy only

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ruxolitinib

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis

and

- ○ A classification of risk of intermediate-2 or high-risk myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS

or

- ○ A classification of risk of intermediate-1 myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS

and

- ○ Patient has severe disease-related symptoms that are resistant, refractory or intolerant to available therapy

and

- ○ A maximum dose of 20 mg twice daily is to be given

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The treatment remains appropriate and the patient is benefiting from treatment

and

- ○ A maximum dose of 20 mg twice daily is to be given

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Alectinib

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has locally advanced, or metastatic, unresectable, non-small cell lung cancer

and

- ○ There is documentation confirming that the patient has an ALK tyrosine kinase gene rearrangement using an appropriate ALK test

and

- ○ Patient has an ECOG performance score of 0-2

CONTINUATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ No evidence of progressive disease according to RECIST criteria

and

- ○ The patient is benefitting from and tolerating treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Palbociclib (Ibrance)

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has unresectable locally advanced or metastatic breast cancer
- **and** ○ There is documentation confirming disease is hormone-receptor positive and HER2-negative
- **and** ○ Patient has an ECOG performance score of 0-2
- **and**
  - ○ Disease has relapsed or progressed during prior endocrine therapy
  - **or**
    - ○ Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal or without menstrual-potential state
    - **and** ○ Patient has not received prior systemic treatment for metastatic disease
- **and** ○ Treatment must be used in combination with an endocrine partner
- **and** ○ Patient has not received prior funded treatment with a CDK4/6 inhibitor

or

- ○ Patient has an active Special Authority approval for ribociclib
- **and** ○ Patient has experienced a grade 3 or 4 adverse reaction to ribociclib that cannot be managed by dose reductions and requires treatment discontinuation
- **and** ○ Treatment must be used in combination with an endocrine partner
- **and** ○ There is no evidence of progressive disease since initiation of ribociclib

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Treatment must be used in combination with an endocrine partner
- **and** ○ There is no evidence of progressive disease since initiation of palbociclib

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Midostaurin

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient has a diagnosis of acute myeloid leukaemia

and

- ○ Condition must be FMS tyrosine kinase 3 (FLT3) mutation positive

and

- ○ Patient must not have received a prior line of intensive chemotherapy for acute myeloid leukaemia

and

- ○ Patient is to receive standard intensive chemotherapy in combination with midostaurin only

and

- ○ Midostaurin to be funded for a maximum of 4 cycles

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ribociclib

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has unresectable locally advanced or metastatic breast cancer
- **and** ○ There is documentation confirming disease is hormone-receptor positive and HER2-negative
- **and** ○ Patient has an ECOG performance score of 0-2
- **and**
  - ○ Disease has relapsed or progressed during prior endocrine therapy
  - **or**
    - ○ Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal or without menstrual-potential state
    - **and** ○ Patient has not received prior systemic endocrine treatment for metastatic disease
- **and** ○ Treatment to be used in combination with an endocrine partner
- **and** ○ Patient has not received prior funded treatment with a CDK4/6 inhibitor

or

- ○ Patient has an active Special Authority approval for palbociclib
- **and** ○ Patient has experienced a grade 3 or 4 adverse reaction to palbociclib that cannot be managed by dose reductions and requires treatment discontinuation
- **and** ○ Treatment must be used in combination with an endocrine partner
- **and** ○ There is no evidence of progressive disease since initiation of palbociclib

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Treatment must be used in combination with an endocrine partner
- **and** ○ There is no evidence of progressive disease since initiation of ribociclib

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Lenvatinib

INITIATION – thyroid cancer
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient is currently on treatment with lenvatinib and met all remaining criteria prior to commencing treatment

or

- ○ The patient has locally advanced or metastatic differentiated thyroid cancer

and

- ○ Patient must have symptomatic progressive disease prior to treatment

or

- ○ Patient must progressive disease at critical anatomical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures

and

- ○ A lesion without iodine uptake in a RAI scan

or

- ○ Receiving cumulative RAI greater than or equal to 600 mCi

or

- ○ Experiencing disease progression after a RAI treatment within 12 months

or

- ○ Experiencing disease progression after two RAI treatments administered within 12 months of each other

and

- ○ Patient has thyroid stimulating hormone (TSH) adequately supressed

and

- ○ Patient is not a candidate for radiotherapy with curative intent

and

- ○ Surgery is clinically inappropriate

and

- ○ Patient has an ECOG performance status of 0-2

CONTINUATION – thyroid cancer
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ There is no evidence of disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Lenvatinib *- continued*

INITIATION – unresectable hepatocellular carcinoma
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has unresectable hepatocellular carcinoma

and

- ○ Patient has preserved liver function (Childs-Pugh A)

and

- ○ Transarterial chemoembolisation (TACE) is unsuitable

and

- ○ Patient has an ECOG performance status of 0-2

and

- ○ Patient has not received prior systemic therapy for their disease in the palliative setting

or

- ○ Patient has experienced treatment-limiting toxicity from treatment with atezolizumab with bevacizumab

and

- ○ No disease progression since initiation of atezolizumab with bevacizumab

CONTINUATION – unresectable hepatocellular carcinoma
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ There is no evidence of disease progression

INITIATION – renal cell carcinoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has metastatic renal cell carcinoma

and

- ○ The disease is of predominant clear-cell histology

and

- ○ The patient has documented disease progression following one previous line of treatment

and

- ○ The patient has an ECOG performance status of 0-2

and

- ○ Lenvatinib is to be used in combination with everolimus

or

- ○ Patient has received funded treatment with nivolumab for the second line treatment of metastatic renal cell carcinoma

and

- ○ Patient has experienced treatment limiting toxicity from treatment with nivolumab

and

- ○ Lenvatinib is to be used in combination with everolimus

and

- ○ There is no evidence of disease progression

CONTINUATION – renal cell carcinoma
Re-assessment required after 4 months
Prerequisites (tick box where appropriate)

- ○ There is no evidence of disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Osimertinib

INITIATION – NSCLC – first line
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has locally advanced or metastatic, incurable, non-squamous non-small cell lung cancer (NSCLC)

and

- ○ Patient is treatment naïve

or

- ○ Patient has received prior treatment in the adjuvant setting and/or while awaiting EGFR results

or

- ○ The patient has discontinued gefitinib or erlotinib due to intolerance

and

- ○ The cancer did not progress while on gefitinib or erlotinib

and

- ○ There is documentation confirming that the cancer expresses activating mutations of EGFR

and

- ○ Patient has an ECOG performance status 0-3

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

CONTINUATION – NSCLC – first line
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ Response to or stable disease with treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

INITIATION – NSCLC – second line
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has locally advanced or metastatic, incurable, non-squamous non-small cell lung cancer (NSCLC)

and

- ○ Patient has an ECOG performance status 0-3

and

- ○ The patient must have received previous treatment with erlotinib or gefitinib

and

- ○ There is documentation confirming that the cancer expresses T790M mutation of EGFR following progression on or after erlotinib or gefitinib

and

- ○ The treatment must be given as monotherapy

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

CONTINUATION – NSCLC – second line
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Axitinib

INITIATION
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has metastatic renal cell carcinoma

and

- ○ The disease is of predominant clear cell histology

and

- ○ The patient has documented disease progression following one previous line of treatment

and

- ○ The patient has ECOG performance status of 0-2

CONTINUATION
Re-assessment required after 4 months
Prerequisites (tick box where appropriate)

- ○ No evidence of disease progression.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Crizotinib

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has locally advanced or metastatic, unresectable, non-squamous non-small cell lung cancer

and

- ○ There is documentation confirming that the patient has a ROS1 rearrangement using an appropriate ROS1 test

and

- ○ Patient has ECOG performance score of 0-3

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

CONTINUATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Response to treatment has been determined by comparable radiological assessment following the most recent treatment period

and

- ○ No evidence of disease progression.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Dabrafenib

INITIATION – stage III or IV resected melanoma - adjuvant
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment

or

- ○ The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a)

or

- ○ The individual has received neoadjuvant treatment with a PD-1/PD-L1 inhibitor

and

- ○ Adjuvant treatment with dabrafenib is required

and

- ○ The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma

and

- ○ Treatment must be adjuvant to complete surgical resection

and

- ○ Treatment must be initiated within 13 weeks of surgical resection, unless delay is necessary due to post-surgery recovery (see note b)

and

- ○ The individual has a confirmed BRAF mutation

and

- ○ Dabrafenib must be administered in combination with trametinib

and

- ○ The individual has ECOG performance score 0-2

Note:

a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition

b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Dabrafenib *- continued*

CONTINUATION – stage III or IV resected melanoma - adjuvant
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ No evidence of disease recurrence

and

- ○ Dabrafenib must be administered in combination with trametinib

and

- ○ Treatment to be discontinued at signs of disease recurrence or at completion of 12 months' total treatment course, including any systemic neoadjuvant treatment

or

- ○ The individual has received adjuvant treatment with a BRAF/MEK inhibitor

and

- ○ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV

and

- ○ The individual meets initiation criteria for dabrafenib for unresectable or metastatic melanoma

or

- ○ The individual has received adjuvant treatment with a BRAF/MEK inhibitor

and

- ○ The individual has received a BRAF/MEK inhibitor for unresectable or metastatic melanoma

and

- ○ The individual meets continuation criteria for dabrafenib for unresectable or metastatic melanoma

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Dabrafenib *- continued*

INITIATION – unresectable or metastatic melanoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment

or

- ○ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

and

- ○ The individual has ECOG performance score 0-2

and

- ○ The individual has confirmed BRAF mutation

and

- ○ Dabrafenib must be administered in combination with trametinib

and

- ○ The individual has been diagnosed in the metastatic or unresectable stage III or IV setting

or

- ○ The individual did not receive treatment in the adjuvant setting with a BRAF/MEK inhibitor

or

- ○ The individual received treatment in the adjuvant setting with a BRAF/MEK inhibitor

and

- ○ The individual did not experience disease recurrence while on treatment with that BRAF/MEK inhibitor

and

- ○ The individual did not experience disease recurrence within six months of completing adjuvant treatment with a BRAF/MEK inhibitor

CONTINUATION – unresectable or metastatic melanoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual's disease has had a complete response to treatment

or

- ○ The individual's disease has had a partial response to treatment

or

- ○ The individual has stable disease with treatment

and

- ○ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Trametinib

INITIATION – stage III or IV resected melanoma - adjuvant
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment

or

- ○ The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a)

or

- ○ The individual has received neoadjuvant treatment with a PD-1/PD-L1 inhibitor

and

- ○ Adjuvant treatment with trametinib is required

and

- ○ The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma

and

- ○ Treatment must be adjuvant to complete surgical resection

and

- ○ Treatment must be initiated within 13 weeks of surgical resection, unless delay is necessary due to post-surgery recovery (see note b)

and

- ○ The individual has a confirmed BRAF mutation

and

- ○ Trametinib must be administered in combination with dabrafenib

and

- ○ The individual has ECOG performance score 0-2

Note:

a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition

b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Trametinib *- continued*

CONTINUATION – stage III or IV resected melanoma - adjuvant
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ No evidence of disease recurrence

and

- ○ Trametinib must be administered in combination with dabrafenib

and

- ○ Treatment to be discontinued at signs of disease recurrence or at completion of 12 months' total treatment course, including any systemic neoadjuvant treatment

or

- ○ The individual has received adjuvant treatment with a BRAF/MEK inhibitor

and

- ○ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV

and

- ○ The individual meets initiation criteria for trametinib for unresectable or metastatic melanoma

or

- ○ The individual has received adjuvant treatment with a BRAF/MEK inhibitor

and

- ○ The individual has received a BRAF/MEK inhibitor for unresectable or metastatic melanoma

and

- ○ The individual meets continuation criteria for trametinib for unresectable or metastatic melanoma

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Trametinib *- continued*

INITIATION – unresectable or metastatic melanoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment

or

- ○ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

and

- ○ The individual has ECOG performance score 0-2

and

- ○ The individual has confirmed BRAF mutation

and

- ○ Trametinib must be administered in combination with dabrafenib

and

- ○ The individual has been diagnosed in the metastatic or unresectable stage III or IV setting

or

- ○ The individual did not receive treatment in the adjuvant setting with a BRAF/MEK inhibitor

or

- ○ The individual received treatment in the adjuvant setting with a BRAF/MEK inhibitor

and

- ○ The individual did not experience disease recurrence while on treatment with that BRAF/MEK inhibitor

and

- ○ The individual did not experience disease recurrence within six months of completing adjuvant treatment with a BRAF/MEK inhibitor

CONTINUATION – unresectable or metastatic melanoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual's disease has had a complete response to treatment

or

- ○ The individual's disease has had a partial response to treatment

or

- ○ The individual has stable disease with treatment

and

- ○ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Dasatinib

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist or any relevant practitioner on the recommendation of a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis or accelerated phase

or

- ○ The patient has a diagnosis of Philadelphia chromosome-positive acute lymphoid leukaemia (Ph+ ALL)

or

- ○ The patient has a diagnosis of CML in chronic phase

and

- ○ Patient has documented treatment failure* with imatinib

or

- ○ Patient has experienced treatment-limiting toxicity with imatinib precluding further treatment with imatinib

or

- ○ Patient has high-risk chronic-phase CML defined by the Sokal or EURO scoring system

CONTINUATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist or any relevant practitioner on the recommendation of a haematologist , or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Lack of treatment failure while on dasatinib*

and

- ○ Dasatinib treatment remains appropriate and the patient is benefiting from treatment

Note: *treatment failure for CML as defined by Leukaemia Net Guidelines.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Erlotinib

INITIATION
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC)

and

- ○ There is documentation confirming that the disease expresses activating mutations of EGFR

and

- ○ Patient is treatment naive

or

- ○ Patient has received prior treatment in the adjuvant setting and/or while awaiting EGFR results

or

- ○ The patient has discontinued osimertinib or getitinib due to intolerance

and

- ○ The cancer did not progress while on osimertinib or gefitinib

CONTINUATION
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ Radiological assessment (preferably including CT scan) indicates NSCLC has not progressed

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sunitinib

INITIATION – RCC
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has metastatic renal cell carcinoma

and

- ○ The patient has not previously received funded sunitinib

CONTINUATION – RCC
Re-assessment required after 4 months
Prerequisites (tick box where appropriate)

- ○ No evidence of disease progression

INITIATION – GIST
Re-assessment required after 3 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST)

and

- ○ The patient's disease has progressed following treatment with imatinib

or

- ○ The patient has documented treatment-limiting intolerance, or toxicity to, imatinib

CONTINUATION – GIST
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

The patient has responded to treatment or has stable disease as determined by Choi's modified CT response evaluation criteria as follows:

- ○ The patient has had a complete response (disappearance of all lesions and no new lesions)

or

- ○ The patient has had a partial response (a decrease in size of 10% or more or decrease in tumour density in Hounsfield Units (HU) of 15% or more on CT and no new lesions and no obvious progression of non-measurable disease)

or

- ○ The patient has stable disease (does not meet criteria the two above) and does not have progressive disease and no symptomatic deterioration attributed to tumour progression

and

- ○ The treatment remains appropriate and the patient is benefiting from treatment

CONTINUATION – GIST pandemic circumstances
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST)

and

- ○ The patient is clinically benefiting from treatment and continued treatment remains appropriate

and

- ○ Sunitinib is to be discontinued at progression

and

- ○ The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sunitinib *- continued*

Note: GIST - It is recommended that response to treatment be assessed using Choi's modified CT response evaluation criteria (J Clin Oncol, 2007, 25:1753-1759). Progressive disease is defined as either: an increase in tumour size of 10% or more and not meeting criteria of partial response (PR) by tumour density (HU) on CT; or: new lesions, or new intratumoral nodules, or increase in the size of the existing intratumoral nodules.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Lapatinib

INITIATION

Prerequisites (tick box where appropriate)

- ○ For continuation use only

CONTINUATION

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- ○ The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology)

and

- ○ The cancer has not progressed at any time point during the previous 12 months whilst on lapatinib

and

- ○ Lapatinib not to be given in combination with trastuzumab

and

- ○ Lapatinib to be discontinued at disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pazopanib

INITIATION
Re-assessment required after 3 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has metastatic renal cell carcinoma of predominantly clear cell histology

and

- ○ The patient is treatment naive

or

- ○ The patient has only received prior cytokine treatment

and

- ○ The patient has an ECOG performance score of 0-2

and

The patient has intermediate or poor prognosis defined as:

- ○ Lactate dehydrogenase level > 1.5 times upper limit of normal

or

- ○ Haemoglobin level < lower limit of normal

or

- ○ Corrected serum calcium level > 10 mg/dL (2.5 mmol/L)

or

- ○ Interval of < 1 year from original diagnosis to the start of systemic therapy

or

- ○ Karnofsky performance score of less than or equal to 70

or

- ○ 2 or more sites of organ metastasis

or

- ○ The patient has metastatic renal cell carcinoma

and

- ○ The patient has discontinued sunitinib within 3 months of starting treatment due to intolerance

and

- ○ The cancer did not progress whilst on sunitinib

and

- ○ Pazopanib to be used for a maximum of 3 months

CONTINUATION
Re-assessment required after 3 months
Prerequisites (tick box where appropriate)

- ○ No evidence of disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Gefitinib

INITIATION
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ❍ Patient has locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC)

and

- ❍ Patient is treatment naive

or

- ❍ Patient has received prior treatment in the adjuvant setting and/or while awaiting EGFR results

or

- ❍ The patient has discontinued osimertinib or erlotinib due to intolerance

and

- ❍ The cancer did not progress whilst on osimertinib or erlotinib

and

- ❍ There is documentation confirming that disease expresses activating mutations of EGFR

CONTINUATION
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ❍ Radiological assessment (preferably including CT scan) indicates NSCLC has not progressed

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Dexrazoxane

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist, paediatric oncologist, haematologist or paediatric haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is to receive treatment with high dose anthracycline given with curative intent

and

- ○ Based on current treatment plan, patient's cumulative lifetime dose of anthracycline will exceed 250mg/m2 doxorubicin equivalent or greater

and

- ○ Dexrazoxane to be administered only whilst on anthracycline treatment

and

- ○ Treatment to be used as a cardioprotectant for a child or young adult

or

- ○ Treatment to be used as a cardioprotectant for secondary malignancy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Abiraterone acetate

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist, radiation oncologist or urologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has prostate cancer

and

- ○ Patient has metastases

and

- ○ Patient's disease is castration resistant

and

- ○ Patient is symptomatic

and

- ○ Patient has disease progression (rising serum PSA) after second line anti-androgen therapy

and

- ○ Patient has ECOG performance score of 0-1

and

- ○ Patient has not had prior treatment with taxane chemotherapy

or

- ○ Patient's disease has progressed following prior chemotherapy containing a taxane

and

- ○ Patient has ECOG performance score of 0-2

and

- ○ Patient has not had prior treatment with abiraterone

CONTINUATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist, radiation oncologist or urologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Significant decrease in serum PSA from baseline

and

- ○ No evidence of clinical disease progression

and

- ○ No initiation of taxane chemotherapy with abiraterone

and

- ○ The treatment remains appropriate and the patient is benefiting from treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Abiraterone acetate *- continued*

CONTINUATION – pandemic circumstances
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ❍ The patient is clinically benefiting from treatment and continued treatment remains appropriate

and

- ❍ Abiraterone acetate to be discontinued at progression

and

- ❍ No initiation of taxane chemotherapy with abiraterone

and

- ❍ The regular renewal requirements cannot be met due to COVID-19 constraints on the health sector

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Fulvestrant

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has oestrogen-receptor positive locally advanced or metastatic breast cancer

and

- ○ Patient has disease progression following prior treatment with an aromatase inhibitor or tamoxifen for their locally advanced or metastatic disease

and

- ○ Treatment to be given at a dose of 500 mg monthly following loading doses

and

- ○ Treatment to be discontinued at disease progression

CONTINUATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Treatment remains appropriate and patient is benefitting from treatment

and

- ○ Treatment to be given at a dose of 500 mg monthly

and

- ○ No evidence of disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Long-acting Somatostatin Analogues

INITIATION – Malignant bowel obstruction

Prerequisites (tick boxes where appropriate)

- ○ The patient has nausea* and vomiting* due to malignant bowel obstruction*

and

- ○ Treatment with antiemetics, rehydration, antimuscarinic agents, corticosteroids and analgesics for at least 48 hours has not been successful

and

- ○ Treatment to be given for up to 4 weeks

Note: Indications marked with * are unapproved indications

INITIATION – acromegaly

Re-assessment required after 3 months

Prerequisites (tick boxes where appropriate)

- ○ The patient has acromegaly

and

- ○ Treatment with surgery and radiotherapy is not suitable or was unsuccessful

or

- ○ Treatment is for an interim period while awaiting the beneficial effects of radiotherapy

and

- ○ Treatment with a dopamine agonist has been unsuccessful

CONTINUATION – acromegaly

Prerequisites (tick box where appropriate)

- ○ Without reassessment for applications where IGF1 levels have decreased since starting treatment

Note: In patients with acromegaly, treatment should be discontinued if IGF1 levels have no decreased 3 months after treatment. In patients treated with radiotherapy treatment should be withdrawn every 2 years, for 1 month, for assessment of remission. Treatment should be stopped where there is biochemical evidence of remission (normal IGF1 levels) following treatment withdrawal for at least 4 weeks.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Long-acting Somatostatin Analogues *- continued*

INITIATION – Other indications

Prerequisites (tick boxes where appropriate)

- ○ VIPomas and glucagonomas - for patients who are seriously ill in order to improve their clinical state prior to definitive surgery

or

- ○ Gastrinoma

and

- ○ Surgery has been unsuccessful

or

- ○ Patient has metastatic disease after treatment with H2 antagonist or proton pump inhibitors has been unsuccessful

or

- ○ Insulinomas

and

- ○ Surgery is contraindicated or has not been successful

or

- ○ For pre-operative control of hypoglycaemia and for maintenance therapy

or

- ○ Carcinoid syndrome (diagnosed by tissue pathology and/or urinary 5HIAA analysis)

and

- ○ Disabling symptoms not controlled by maximal medical therapy

INITIATION – pre-operative acromegaly

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- ○ Patient has acromegaly

and

- ○ Patient has a large pituitary tumour, greater than 10 mm at its widest

and

- ○ Patient is scheduled to undergo pituitary surgery in the next six months

Note: Indications marked with * are unapproved indications

Note: The use of a long-acting somatostatin analogue in patients with fistulae, oesophageal varices, miscellaneous diarrhoea and hypotension will not be funded under Special Authority

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Aminolevulinic acid hydrochloride

INITIATION – high grade malignant glioma

Prerequisites (tick boxes where appropriate)

- ○ Patient has newly diagnosed, untreated, glioblastoma multiforme

and

- ○ Treatment to be used as adjuvant to fluorescence-guided resection

and

- ○ Patient's tumour is amenable to complete resection

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tacrolimus

INITIATION – organ transplant recipients

Prerequisites (tick boxes where appropriate)

- ○ For use in organ transplant recipients

or

- ○ The individual is receiving induction therapy for an organ transplant

INITIATION – non-transplant indications*

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient requires long-term systemic immunosuppression

and

- ○ Ciclosporin has been trialled and discontinued treatment because of unacceptable side effects or inadequate clinical response

or

- ○ Patient is a child with nephrotic syndrome*

Note: Indications marked with * are unapproved indications

I confirm that the above details are correct:

Signed: ..... Date: .....

RS2062 - Etanercept

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept

INITIATION – polyarticular course juvenile idiopathic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or named specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for adalimumab for polyarticular course juvenile idiopathic arthritis (JIA)

and

- ○ The patient has experienced intolerable side effects from adalimumab

or

- ○ The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for polyarticular course JIA

or

- ○ To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- ○ Patient has had polyarticular course JIA for 6 months duration or longer

and

- ○ At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

- ○ Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

- ○ Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate

CONTINUATION – polyarticular course juvenile idiopathic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or named specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- ○ Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline

or

- ○ On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

INITIATION – oligoarticular course juvenile idiopathic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or named specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for adalimumab for oligoarticular course juvenile idiopathic arthritis (JIA)

and

- ○ The patient has experienced intolerable side effects from adalimumab

or

- ○ The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for oligoarticular course JIA

or

- ○ To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- ○ Patient has had oligoarticular course JIA for 6 months duration or longer

and

- ○ At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

- ○ Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

- ○ High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate

CONTINUATION – oligoarticular course juvenile idiopathic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or named specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- ○ Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baselinee

or

- ○ On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

INITIATION – Arthritis - rheumatoid
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for adalimumab for rheumatoid arthritis

and

- ○ The patient has experienced intolerable side effects

or

- ○ The patient has received insufficient benefit to meet the renewal criteria for rheumatoid arthritis

or

- ○ Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer

and

- ○ Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- ○ Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated)

and

- ○ Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate at maximum tolerated doses (unless contraindicated)

and

- ○ Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin

or

- ○ Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate

and

- ○ Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints

or

- ○ Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

CONTINUATION – Arthritis - rheumatoid
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- ○ Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ○ On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

and

- ○ Etanercept to be administered at doses no greater than 50 mg every 7 days

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

INITIATION – ankylosing spondylitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

or

- ○ The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis

and

or

- ○ The patient has experienced intolerable side effects from adalimumab
- ○ The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for ankylosing spondylitis

or

- ○ Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months

and

- ○ Patient has low back pain and stiffness that is relieved by exercise but not by rest

and

- ○ Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan

and

- ○ Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis

and

or

- ○ Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right)
- ○ Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender (see Notes)

and

- ○ Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale

Note: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of starting treatment.
Average normal chest expansion corrected for age and gender:

Age	Male	Female
18-24	7.0 cm	5.5 cm
25-34	7.5 cm	5.5 cm
35-44	6.5 cm	4.5 cm
45-54	6.0 cm	5.0 cm
55-64	5.5 cm	4.0 cm
65-74	4.0 cm	4.0 cm
75+	3.0 cm	2.5 cm

I confirm that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

CONTINUATION – ankylosing spondylitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Following 12 weeks' initial treatment and for subsequent renewals, treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less

and

- ○ Physician considers that the patient has benefited from treatment and that continued treatment is appropriate

and

- ○ Etanercept to be administered at doses no greater than 50 mg every 7 days

INITIATION – psoriatic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for adalimumab or secukinumab for psoriatic arthritis

and

- ○ The patient has experienced intolerable side effects from adalimumab or secukinumab

or

- ○ The patient has received insufficient benefit from adalimumab or secukinumab to meet the renewal criteria for adalimumab or secukinumab for psoriatic arthritis

or

- ○ Patient has had severe active psoriatic arthritis for six months duration or longer

and

- ○ Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose

and

- ○ Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses)

and

- ○ Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints

or

- ○ Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

- ○ Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application

or

- ○ Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour

or

- ○ ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

CONTINUATION – psoriatic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ❍ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ❍ The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior etanercept treatment in the opinion of the treating physician

and

- ❍ Etanercept to be administered at doses no greater than 50 mg every 7 days

INITIATION – severe chronic plaque psoriasis, prior TNF use
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ❍ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ The patient has had an initial Special Authority approval for adalimumab for severe chronic plaque psoriasis

and

- ❍ The patient has experienced intolerable side effects from adalimumab

or

- ❍ The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe chronic plaque psoriasis

and

- ❍ Patient must be reassessed for continuation after 3 doses

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

INITIATION – severe chronic plaque psoriasis, treatment-naive
Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis

or

❍ Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis

or

❍ Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10

and

❍ Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin

and

❍ A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course

and

❍ The most recent PASI or DLQI assessment is no more than 1 month old at the time of initiation

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand, foot, genital or flexural areas at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and for the face, palm of a hand or sole of a foot the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

CONTINUATION – severe chronic plaque psoriasis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient had "whole body" severe chronic plaque psoriasis at the start of treatment
  and
  - ○ Following each prior etanercept treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-etanercept treatment baseline value
    or
  - ○ Following each prior etanercept treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value

or

- ○ Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment
  and
  - ○ Following each prior etanercept treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values
    or
  - ○ Following each prior etanercept treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-etanercept treatment baseline value

or

- ○ Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment
  and
  - ○ The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value
    or
  - ○ Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing etanercept

and

- ○ Etanercept to be administered at doses no greater than 50 mg every 7 days

INITIATION – pyoderma gangrenosum
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pyoderma gangrenosum*

and

- ○ Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and not received an adequate response

and

- ○ A maximum of 8 doses

Note: Indications marked with * are unapproved indications.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

CONTINUATION – pyoderma gangrenosum
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has shown clinical improvement

and

- ○ Patient continues to require treatment

and

- ○ A maximum of 8 doses

INITIATION – adult-onset Still's disease
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for etanercept for adult-onset Still's disease (AOSD)

or

- ○ The patient has been started on tocilizumab for AOSD in a Health NZ Hospital

and

- ○ The patient has experienced intolerable side effects from etanercept and/or tocilizumab

or

- ○ The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or tocilizumab such that they do not meet the renewal criteria for AOSD

or

- ○ Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430)

and

- ○ Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal antiinflammatory drugs (NSAIDs) and methotrexate

and

- ○ Patient has persistent symptoms of disabling poorly controlled and active disease

CONTINUATION – adult-onset Still's disease
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a sustained improvement in inflammatory markers and functional status

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

INITIATION – undifferentiated spondyloarthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

- ○ Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose

and

- ○ Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day (or maximum tolerated dose)

and

- ○ Patient has tried and not responded to at least three months of leflunomide at a dose of up to 20 mg daily (or maximum tolerated dose)

and

- ○ Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application

or

- ○ Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour measured no more than one month prior to the date of this application

or

- ○ ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

Note: Indications marked with * are unapproved indications.

CONTINUATION – undifferentiated spondyloarthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Applicant is a rheumatologist

or

- ○ Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment

and

- ○ Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ○ The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior etanercept treatment in the opinion of the treating physician

and

- ○ Etanercept to be administered at doses no greater than 50 mg dose every 7 days

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Bevacizumab

INITIATION – Recurrent Respiratory Papillomatosis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an otolaryngologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Maximum of 6 doses

and

- ○ The patient has recurrent respiratory papillomatosis

and

- ○ The treatment is for intra-lesional administration

CONTINUATION – Recurrent Respiratory Papillomatosis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an otolaryngologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Maximum of 6 doses

and

- ○ The treatment is for intra-lesional administration

and

- ○ There has been a reduction in surgical treatments or disease regrowth as a result of treatment

INITIATION – ocular conditions
Prerequisites (tick boxes where appropriate)

- ○ Ocular neovascularisation

or

- ○ Exudative ocular angiopathy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ranibizumab

INITIATION – Wet Age Related Macular Degeneration
Re-assessment required after 3 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an ophthalmologist or nurse practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Wet age-related macular degeneration (wet AMD)

or

- ○ Polypoidal choroidal vasculopathy

or

- ○ Choroidal neovascular membrane from causes other than wet AMD

and

- ○ The patient has developed severe endophthalmitis or severe posterior uveitis following treatment with bevacizumab

or

- ○ There is worsening of vision or failure of retina to dry despite three intraocular injections of bevacizumab four weeks apart

and

- ○ There is no structural damage to the central fovea of the treated eye

and

- ○ Patient has not previously been treated with aflibercept for longer than 3 months

or

- ○ Patient has current approval to use aflibercept for treatment of wAMD and was found to be intolerant to aflibercept within 3 months

CONTINUATION – Wet Age Related Macular Degeneration
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an ophthalmologist or nurse practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Documented benefit must be demonstrated to continue

and

- ○ Patient's vision is 6/36 or better on the Snellen visual acuity score

and

- ○ There is no structural damage to the central fovea of the treated eye

I confirm that the above details are correct:

Signed: ..... Date: .....

RS2124 - Infliximab

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab

INITIATION – Graft vs host disease

Prerequisites (tick box where appropriate)

- ○ Patient has steroid-refractory acute graft vs. host disease of the gut

INITIATION – rheumatoid arthritis

Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis

and

- ○ The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept

or

- ○ Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept

and

- ○ Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

CONTINUATION – rheumatoid arthritis

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- ○ Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ○ The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

and

- ○ Infliximab to be administered at doses no greater than 3 mg/kg every 8 weeks

INITIATION – ankylosing spondylitis

Re-assessment required after 3 months

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis

and

- ○ The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept

or

- ○ Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

CONTINUATION – ankylosing spondylitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Following 12 weeks of infliximab treatment, BASDAI has improved by 4 or more points from pre-infliximab baseline on a 10 point scale, or by 50%, whichever is less

and

- ○ Physician considers that the patient has benefited from treatment and that continued treatment is appropriate

and

- ○ Infliximab to be administered at doses no greater than 5 mg/kg every 6-8 weeks

INITIATION – psoriatic arthritis
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis

and

- ○ The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept and/or secukinumab

or

- ○ Following 3-4 months' initial treatment with adalimumab and/or etanercept and/or secukinumab, the patient did not meet the renewal criteria for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis.

CONTINUATION – psoriatic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ○ The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior infliximab treatment in the opinion of the treating physician

and

- ○ Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

INITIATION – severe ocular inflammation
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has had an initial Special Authority approval for adalimumab for severe ocular inflammation

and

- ○ The patient has experienced intolerable side effects from adalimumab

or

- ○ The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe ocular inflammation

or

- ○ Patient has severe, vision-threatening ocular inflammation requiring rapid control

and

- ○ Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms

or

- ○ Patient developed new inflammatory symptoms while receiving high dose steroids

or

- ○ Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms

CONTINUATION – severe ocular inflammation
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has had a good clinical response following 3 initial doses

or

- ○ Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema)

or

- ○ Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

INITIATION – chronic ocular inflammation
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has had an initial Special Authority approval for adalimumab for chronic ocular inflammation

and

- ○ The patient has experienced intolerable side effects from adalimumab

or

- ○ The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for chronic ocular inflammation

or

- ○ Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss

and

- ○ Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective

or

- ○ Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at therapeutic dose

or

- ○ Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate

CONTINUATION – chronic ocular inflammation
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has had a good clinical response following 3 initial doses

or

- ○ Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema)

or

- ○ Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

INITIATION – Pulmonary sarcoidosis
Prerequisites (tick boxes where appropriate)

- ○ Patient has life-threatening pulmonary sarcoidosis that is refractory to other treatments

and

- ○ Treatment is to be prescribed by, or has been recommended by, a physician with expertise in the treatment of pulmonary sarcoidosis

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

INITIATION – Crohn's disease (adults)
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has active Crohn's disease

and

- ○ Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10

or

- ○ Patient has extensive small intestine disease affecting more than 50 cm of the small intestine

or

- ○ Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection

or

- ○ Patient has an ileostomy or colostomy, and has intestinal inflammation

and

- ○ Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids

CONTINUATION – Crohn's disease (adults)
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced by 3 points, from when the patient was initiated on infliximab

or

- ○ CDAI score is 150 or less, or HBI is 4 or less

or

- ○ The patient has demonstrated an adequate response to treatment but CDAI score and/or HBI score cannot be assessed

and

- ○ Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle

INITIATION – Crohn's disease (children)
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Paediatric patient has active Crohn's disease

and

- ○ Patient has a PCDAI score of greater than or equal to 30

or

- ○ Patient has extensive small intestine disease

and

- ○ Patient has tried but experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and corticosteroids

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

CONTINUATION – Crohn's disease (children)
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab

or

- ○ PCDAI score is 15 or less

or

- ○ The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed

and

- ○ Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle

INITIATION – fistulising Crohn's disease
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has confirmed Crohn's disease

and

- ○ Patient has one or more complex externally draining enterocutaneous fistula(e)

or

- ○ Patient has one or more rectovaginal fistula(e)

or

- ○ Patient has complete peri-anal fistula

CONTINUATION – fistulising Crohn's disease
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The number of open draining fistulae have decreased from baseline by at least 50%

or

- ○ There has been a marked reduction in drainage of all fistula(e) from baseline (in the case of adult patients, as demonstrated by a reduction in the Fistula Assessment score), together with less induration and patient reported pain

and

- ○ Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle

I confirm that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

INITIATION – acute fulminant ulcerative colitis
Re-assessment required after 6 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has acute, fulminant ulcerative colitis

and

- ○ Treatment with intravenous or high dose oral corticosteroids has not been successful

CONTINUATION – fulminant ulcerative colitis
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months

and

- ○ Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle

INITIATION – ulcerative colitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has active ulcerative colitis

and

- ○ Patients SCCAI is greater than or equal to 4

or

- ○ Patients PUCAI score is greater than or equal to 20

and

- ○ Patient has experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and systemic corticosteroids

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

CONTINUATION – ulcerative colitis
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab

or

- ○ The PUCAI score has reduced by 30 points or more from the PUCAI score when the patient was initiated on infliximab

and

- ○ Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle

INITIATION – plaque psoriasis
Re-assessment required after 3 doses
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has had an initial Special Authority approval for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis

and

- ○ Patient has experienced intolerable side effects from adalimumab, etanercept or secukinumab

or

- ○ Patient has received insufficient benefit from adalimumab, etanercept or secukinumab to meet the renewal criteria for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis

or

- ○ Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis

or

- ○ Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis

or

- ○ Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10

and

- ○ Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, cyclosporin, or acitretin

and

- ○ A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course

and

- ○ The most recent PASI assessment is no more than 1 month old at the time of initiation

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand, foot, genital or flexural areas at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and for the face, palm of a hand or sole of a foot the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

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Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

CONTINUATION – plaque psoriasis
Re-assessment required after 3 doses
Prerequisites (tick boxes where appropriate)

- ○ Patient had "whole body" severe chronic plaque psoriasis at the start of treatment
  and
- ○ Following each prior infliximab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-infliximab treatment baseline value

or

- ○ Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment
  and
- ○ Following each prior infliximab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values
  or
- ○ Following each prior infliximab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-infliximab treatment baseline value

or

- ○ Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment
  and
- ○ The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value
  or
- ○ Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing infliximab

and

- ○ Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks

INITIATION – neurosarcoidosis
Re-assessment required after 18 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Biopsy consistent with diagnosis of neurosarcoidosis
  and
- ○ Patient has CNS involvement
  and
- ○ Patient has steroid-refractory disease
  and
- ○ IV cyclophosphamide has been tried
  or
- ○ Treatment with IV cyclophosphamide is clinically inappropriate

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

CONTINUATION – neurosarcoidosis
Re-assessment required after 18 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ A withdrawal period has been tried and the patient has relapsed

or

- ○ A withdrawal period has been considered but would not be clinically appropriate

and

- ○ There has been a marked reduction in prednisone dose

and

- ○ There has been an improvement in MRI appearances

or

- ○ Marked improvement in other symptomology

INITIATION – severe Behcet's disease
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has severe Behcet's disease which is significantly impacting the patient's quality of life (see Notes)

and

- ○ The patient has severe ocular, neurological and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s) (see Notes)

or

- ○ The patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has not responded adequately to two or more treatment appropriate for the particular symptom(s) (see Notes)

and

- ○ The patient is experiencing significant loss of quality of life

Note:

a) Behcet's disease diagnosed according to the International Study Group for Behcet's Disease. Lancet 1990;335(8697):1078-80. Quality of life measured using an appropriate quality of life scale such as that published in Gilworth et al J Rheumatol. 2004;31:931-7.

b) Treatments appropriate for the particular symptoms are those that are considered standard conventional treatments for these symptoms, for example intravenous/oral steroids and other immunosuppressants for ocular symptoms; azathioprine, steroids, thalidomide, interferon alpha and ciclosporin for mucocutaneous symptoms; and colchicine, steroids and methotrexate for rheumatological symptoms.

CONTINUATION – severe Behcet's disease
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has had a good clinical response to initial treatment with measurably improved quality of life

and

- ○ Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

INITIATION – pyoderma gangrenosum
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pyoderma gangrenosum*

and

- ○ Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and not received an adequate response

and

- ○ A maximum of 8 doses

Note: Indications marked with * are unapproved indications.

CONTINUATION – pyoderma gangrenosum
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has shown clinical improvement

and

- ○ Patient continues to require treatment

and

- ○ A maximum of 8 doses

INITIATION – Inflammatory bowel arthritis (axial)
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has a diagnosis of active ulcerative colitis or active Crohn's disease

and

- ○ Patient has had axial inflammatory pain for six months or more

and

- ○ Patient is unable to take NSAIDs

and

- ○ Patient has unequivocal sacroiliitis demonstrated by radiological imaging or MRI

and

- ○ Patient has not experienced an adequate response to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist

and

- ○ Patient has a BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment

CONTINUATION – Inflammatory bowel arthritis (axial)
Re-assessment required after 2 years
Prerequisites (tick box where appropriate)

- ○ Where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10-point scale, or an improvement in BASDAI of 50%, whichever is less

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

INITIATION – Inflammatory bowel arthritis (peripheral)
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has a diagnosis of active ulcerative colitis or active Crohn's disease

and

- ○ Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular

and

- ○ Patient has tried and not experienced a response to at least three months of methotrexate or azathioprine at a maximum tolerated dose (unless contraindicated)

and

- ○ Patient has tried and not experienced a response to at least three months of sulfasalazine at a maximum tolerated dose (unless contraindicated)

and

- ○ Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application

or

- ○ Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application

or

- ○ ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

CONTINUATION – Inflammatory bowel arthritis (peripheral)
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Following initial treatment, patient has experienced at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ○ Patient has experienced at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician

INITIATION – immune checkpoint inhibitor toxicity in malignancy*
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual requires treatment for moderate to severe autoimmune toxicity following immune checkpoint inhibitor treatment for malignancy

and

- ○ The individual has received insufficient benefit from use of corticosteroids

and

- ○ Infliximab is to be administered at up to 5mg/kg for up to four doses

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

CONTINUATION – immune checkpoint inhibitor toxicity in malignancy*
Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ The individual has shown clinical improvement and ongoing treatment is required

and

❍ Infliximab is to be administered at up to 5mg/kg for up to a total of 8 doses

Note: Indications marked with * are unapproved indications.

I confirm that the above details are correct:

Signed: ..... Date: .....

RS2125 - Tocilizumab

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab

INITIATION – cytokine release syndrome
Re-assessment required after 3 doses
Prerequisites (tick boxes where appropriate)

- ○ The patient has developed grade 3 or 4 cytokine release syndrome associated with the administration of blinatumomab for the treatment of acute lymphoblastic leukaemia

and

- ○ Tocilizumab is to be administered at doses no greater than 8 mg/kg IV for a maximum of 3 doses (if less than 30kg, maximum of 12 mg/kg)

or

- ○ The patient is enrolled in the Malaghan Institute of Medical Research ENABLE trial programme

and

- ○ The patient has developed CRS or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) following CAR T-Cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphoma

and

- ○ Tocilizumab is to be administered according to the consensus guidelines for CRS or ICANS for CAR T-cell therapy at doses no greater than 8 mg/kg IV for a maximum of 3 doses

INITIATION – previous use
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient was being treated with tocilizumab prior to 1 February 2019

and

- ○ Rheumatoid arthritis

or

- ○ Systemic juvenile idiopathic arthritis

or

- ○ Adult-onset Still's disease

or

- ○ Polyarticular juvenile idiopathic arthritis

or

- ○ Idiopathic multicentric Castleman's disease

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab *- continued*

INITIATION – Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)
Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ❍ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis

and

- ❍ The patient has experienced intolerable side effects from adalimumab and/or etanercept

or

- ❍ The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis

and

- ❍ The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor

or

- ❍ The patient has been started on rituximab for rheumatoid arthritis in a Health NZ Hospital

and

- ❍ The patient has experienced intolerable side effects from rituximab

or

- ❍ At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab *- continued*

INITIATION – Rheumatoid Arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer

and

- ○ Tocilizumab is to be used as monotherapy

and

- ○ Treatment with methotrexate is contraindicated

or

- ○ Patient has tried and did not tolerate oral and/or parenteral methotrexate

and

- ○ Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of ciclosporin alone or in combination with another agent

or

- ○ Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of leflunomide alone or in combination with another agent

and

- ○ Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints

or

- ○ Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

- ○ Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application

or

- ○ C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

INITIATION – systemic juvenile idiopathic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient diagnosed with systemic juvenile idiopathic arthritis

and

- ○ Patient has tried and not responded to a reasonable trial of all of the following, either alone or in combination: oral or parenteral methotrexate; non-steroidal anti-inflammatory drugs (NSAIDs); and systemic corticosteroids

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab *- continued*

INITIATION – adult-onset Still's disease
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for adalimumab and/or etanercept for adult-onset Still's disease (AOSD)

  or

- ○ The patient has been started on tocilizumab for AOSD in a Health NZ Hospital

and

- ○ The patient has experienced intolerable side effects from adalimumab and/or etanercept

  or

- ○ The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for AOSD

or

- ○ Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430)

and

- ○ Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal antiinflammatory drugs (NSAIDs) and methotrexate

and

- ○ Patient has persistent symptoms of disabling poorly controlled and active disease

INITIATION – polyarticular juvenile idiopathic arthritis
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for both etanercept and adalimumab for polyarticular course juvenile idiopathic arthritis (JIA)

and

- ○ The patient has experienced intolerable side effects, or has received insufficient benefit from, both etanercept and adalimumab

or

- ○ Treatment with a tumour necrosis factor alpha inhibitor is contraindicated

and

- ○ Patient has had polyarticular course JIA for 6 months duration or longer

and

- ○ To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- ○ At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose)

  or

- ○ Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose)

  or

- ○ Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab *- continued*

INITIATION – idiopathic multicentric Castleman's disease
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has severe HHV-8 negative idiopathic multicentric Castleman's disease

and

- ○ Treatment with an adequate trial of corticosteroids has proven ineffective

and

- ○ Tocilizumab to be administered at doses no greater than 8 mg/kg IV every 3-4 weeks

INITIATION – moderate to severe COVID-19
Re-assessment required after 1 dose
Prerequisites (tick boxes where appropriate)

- ○ Patient has confirmed (or probable) COVID-19

and

- ○ Oxygen saturation of < 92% on room air, or requiring supplemental oxygen

and

- ○ Patient is receiving adjunct systemic corticosteroids, or systemic corticosteroids are contraindicated

and

- ○ Tocilizumab is to be administered at doses no greater than 8mg/kg IV for a maximum of one dose

and

- ○ Tocilizumab is not to be administered in combination with barcitinib

CONTINUATION – Rheumatoid Arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Following 6 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ○ On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

CONTINUATION – systemic juvenile idiopathic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Following up to 6 months' initial treatment, the patient has achieved at least an American College of Rheumatology paediatric 30% improvement criteria (ACR Pedi 30) response from baseline

or

- ○ On subsequent reapplications, the patient demonstrates at least a continuing ACR Pedi 30 response from baseline

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab *- continued*

CONTINUATION – adult-onset Still's disease
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a sustained improvement in inflammatory markers and functional status

CONTINUATION – polyarticular juvenile idiopathic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- ○ Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline

or

- ○ On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

CONTINUATION – idiopathic multicentric Castleman's disease
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The treatment remains appropriate and the patient has a sustained improvement in inflammatory markers and functional status

INITIATION – immune checkpoint inhibitor toxicity in malignancy*
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual requires treatment for moderate to severe autoimmune toxicity following immune checkpoint inhibitor treatment for malignancy

and

- ○ The individual has received insufficient benefit from use of corticosteroids

and

- ○ Tocilizumab is to be administered at a maximum dose of 8 mg/kg fortnightly

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab *- continued*

CONTINUATION – immune checkpoint inhibitor toxicity in malignancy*
Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ The individual has shown clinical improvement and ongoing treatment is required

and

❍ Tocilizumab is to be administered at a maximum dose of 8 mg/kg fortnightly

Note: Indications marked with * are unapproved indications.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Omalizumab

INITIATION – severe asthma
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a clinical immunologist or respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient must be aged 6 years or older

and

- ○ Patient has a diagnosis of severe asthma

and

- ○ Past or current evidence of atopy, documented by skin prick testing or RAST

and

- ○ Total serum human immunoglobulin E (IgE) between 76 IU/mL and 1300 IU/ml at baseline

and

- ○ Proven adherence with optimal inhaled therapy including high dose inhaled corticosteroid (budesonide 1,600 mcg per day or fluticasone propionate 1,000 mcg per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 mcg bd or eformoterol 12 mcg bd) for at least 12 months, unless contraindicated or not tolerated

and

- ○ Patient has received courses of systemic corticosteroids equivalent to at least 28 days treatment in the past 12 months, unless contraindicated or not tolerated

or

- ○ Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral steroids

and

- ○ Patient has an Asthma Control Test (ACT) score of 10 or less

and

- ○ Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 26 weeks after the first dose to assess response to treatment

CONTINUATION – severe asthma
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ An increase in the Asthma Control Test (ACT) score of at least 5 from baseline

and

- ○ A reduction in the maintenance oral corticosteroid dose or number of exacerbations of at least 50% from baseline

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Omalizumab *- continued*

INITIATION – severe chronic spontaneous urticaria
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a clinical immunologist or dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient must be aged 12 years or older

and

- ○ Patient is symptomatic with Urticaria Activity Score 7 (UAS7) of 20 or above

and

- ○ Patient has a Dermatology life quality index (DLQI) of 10 or greater

and

- ○ Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and ciclosporin (> 3 mg/kg day) for at least 6 weeks

or

- ○ Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and at least 3 courses of systemic corticosteroids (> 20 mg prednisone per day for at least 5 days) in the previous 6 months

or

- ○ Patient has developed significant adverse effects whilst on corticosteroids or ciclosporin

and

- ○ Treatment to be stopped if inadequate response* following 4 doses

or

- ○ Complete response* to 6 doses of omalizumab

CONTINUATION – severe chronic spontaneous urticaria
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a clinical immunologist or dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has previously had a complete response* to 6 doses of omalizumab

or

- ○ Patient has previously had a complete response* to 6 doses of omalizumab

and

- ○ Patient has relapsed after cessation of omalizumab therapy

Note: *Inadequate response defined as less than 50% reduction in baseline UAS7 and DLQI score, or an increase in Urticaria Control Test (UCT) score of less than 4 from baseline. Patient is to be reassessed for response after 4 doses of omalizumab. Complete response is defined as UAS7 less than or equal to 6 and DLQI less than or equal to 5; or UCT of 16. Relapse of chronic urticaria on stopping prednisone/ciclosporin does not justify the funding of omalizumab.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Siltuximab

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has severe HHV-8 negative idiopathic multicentric Castleman's Disease

and

- ○ Treatment with an adequate trial of corticosteroids has proven ineffective

and

- ○ Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a haematologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The treatment remains appropriate and the patient has sustained improvement in inflammatory markers and functional status

I confirm that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Obinutuzumab

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has progressive Binet stage A, B or C CD20+ chronic lymphocytic leukaemia requiring treatment

and

- ○ The patient is obinutuzumab treatment naive

and

- ○ The patient is not eligible for full dose FCR due to comorbidities with a score > 6 on the Cumulative Illness Rating Scale (CIRS) or reduced renal function (creatinine clearance < 70mL/min)

and

- ○ Patient has adequate neutrophil and platelet counts* unless the cytopenias are a consequence of marrow infiltration by CLL

and

- ○ Patient has good performance status

and

- ○ Obinutuzumab to be administered at a maximum cumulative dose of 8,000 mg and in combination with chlorambucil for a maximum of 6 cycles

Note: Chronic lymphocytic leukaemia includes small lymphocytic lymphoma. Comorbidity refers only to illness/impairment other than CLL induced illness/impairment in the patient. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with obinutuzumab is expected to improve symptoms and improve ECOG score to < 2.
* greater than or equal to 1.5×10^9/L and platelets greater than or equal to 75×10^9/L

INITIATION – follicular / marginal zone lymphoma
Re-assessment required after 9 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has follicular lymphoma

or

- ○ Patient has marginal zone lymphoma

and

- ○ Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemo-immunotherapy regimen*

and

- ○ Patient has an ECOG performance status of 0-2

and

- ○ Patient has been previously treated with no more than four chemotherapy regimens

and

- ○ Obinutuzumab to be administered at a maximum dose of 1000 mg for a maximum of 6 cycles in combination with chemotherapy*

Note: * includes unapproved indications

CONTINUATION – follicular / marginal zone lymphoma
Re-assessment required after 24 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has no evidence of disease progression following obinutuzumab induction therapy

and

- ○ Obinutuzumab to be administered at a maximum of 1000 mg every 2 months for a maximum of 2 years

and

- ○ Obinutuzumab to be discontinued at disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pertuzumab

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology)

and

- ○ Patient is chemotherapy treatment naive

or

- ○ Patient has not received prior treatment for their metastatic disease and has had a treatment free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer

and

- ○ The patient has good performance status (ECOG grade 0-1)

and

- ○ Pertuzumab to be administered in combination with trastuzumab

and

- ○ Pertuzumab maximum first dose of 840 mg, followed by maximum of 420 mg every 3 weeks

and

- ○ Pertuzumab to be discontinued at disease progression

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology)

and

- ○ The cancer has not progressed at any time point during the previous 12 months whilst on pertuzumab and trastuzumab

or

- ○ Patient has previously discontinued treatment with pertuzumab and trastuzumab for reasons other than severe toxicity or disease progression

and

- ○ Patient has signs of disease progression

and

- ○ Disease has not progressed during previous treatment with pertuzumab and trastuzumab

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Cetuximab

INITIATION – head and neck cancer, locally advanced

Prerequisites (tick boxes where appropriate)

- ○ Patient has locally advanced, non-metastatic, squamous cell cancer of the head and neck

and

- ○ Cisplatin is contraindicated or has resulted in intolerable side effects

and

- ○ Patient has an ECOG performance score of 0-2

and

- ○ To be administered in combination with radiation therapy

INITIATION – colorectal cancer, metastatic

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ○ Patient has metastatic colorectal cancer located on the left side of the colon (see Note)

and

- ○ There is documentation confirming disease is RAS and BRAF wild-type

and

- ○ Patient has an ECOG performance score of 0-2

and

- ○ Patient has not received prior funded treatment with cetuximab

and

- ○ Cetuximab is to be used in combination with chemotherapy

or

- ○ Chemotherapy is determined to not be in the best interest of the patient based on clinician assessment

CONTINUATION – colorectal cancer, metastatic

Re-assessment required after 6 months

Prerequisites (tick box where appropriate)

- ○ No evidence of disease progression

Note: Left-sided colorectal cancer comprises of the distal one-third of the transverse colon, the splenic flexure, the descending colon, the sigmoid colon, or the rectum.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Aflibercept

INITIATION – Wet Age Related Macular Degeneration
Re-assessment required after 3 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an ophthalmologist or nurse practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Wet age-related macular degeneration (wet AMD)

or

- ○ Polypoidal choroidal vasculopathy

or

- ○ Choroidal neovascular membrane from causes other than wet AMD

and

- ○ The patient has developed severe endophthalmitis or severe posterior uveitis following treatment with bevacizumab

or

- ○ There is worsening of vision or failure of retina to dry despite three intraocular injections of bevacizumab four weeks apart

and

- ○ There is no structural damage to the central fovea of the treated eye

and

- ○ Patient has not previously been treated with ranibizumab for longer than 3 months

or

- ○ Patient has current approval to use ranibizumab for treatment of wAMD and was found to be intolerant to ranibizumab within 3 months

or

- ○ Patient has previously* (*before June 2018) received treatment with ranibizumab for wAMD and disease was stable while on treatment

CONTINUATION – Wet Age Related Macular Degeneration
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an ophthalmologist or nurse practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Documented benefit must be demonstrated to continue

and

- ○ Patient's vision is 6/36 or better on the Snellen visual acuity score

and

- ○ There is no structural damage to the central fovea of the treated eye

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Aflibercept *- continued*

INITIATION – Diabetic Macular Oedema
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an ophthalmologist or nurse practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has centre involving diabetic macular oedema (DMO)

and

- ○ Patient's disease is non responsive to 4 doses of intravitreal bevacizumab when administered 4-6 weekly

and

- ○ Patient has reduced visual acuity between 6/9 – 6/36 with functional awareness of reduction in vision

and

- ○ Patient has DMO within central OCT (ocular coherence tomography) subfield > 350 micrometers

and

- ○ There is no centre-involving sub-retinal fibrosis or foveal atrophy

CONTINUATION – Diabetic Macular Oedema
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an ophthalmologist or nurse practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ There is stability or two lines of Snellen visual acuity gain

and

- ○ There is structural improvement on OCT scan (with reduction in intra-retinal cysts, central retinal thickness, and sub-retinal fluid)

and

- ○ Patient's vision is 6/36 or better on the Snellen visual acuity score

and

- ○ There is no centre-involving sub-retinal fibrosis or foveal atrophy

and

- ○ After each consecutive 12 months treatment with aflibercept, patient has retrialled with at least one injection of bevacizumab and had no response

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Secukinumab

INITIATION – severe chronic plaque psoriasis, second-line biologic
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for adalimumab or etanercept, or has trialled infliximab in a Health NZ Hospital, for severe chronic plaque psoriasis

and

- ○ The patient has experienced intolerable side effects from adalimumab, etanercept or infliximab

or

- ○ The patient has received insufficient benefit from adalimumab, etanercept or infliximab

and

- ○ A Psoriasis Area and Severity Index (PASI) assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course

and

- ○ The most recent PASI or DQLI assessment is no more than 1 month old at the time of application

CONTINUATION – severe chronic plaque psoriasis, second-line biologic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient's PASI score has reduced by 75% or more (PASI 75) as compared to baseline PASI prior to commencing secukinumab

or

- ○ Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab

and

- ○ Secukinumab to be administered at a maximum dose of 300 mg monthly

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Secukinumab *- continued*

INITIATION – severe chronic plaque psoriasis, first-line biologic
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ❍ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis

or

- ❍ Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis

or

- ❍ Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10

and

- ❍ Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin

and

- ❍ A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course

and

- ❍ The most recent PASI or DQLI assessment is no more than 1 month old at the time of application

Note: A treatment course is defined as a minimum of 12 weeks of treatment. "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand, foot, genital or flexural areas, at least 2 of the 3 PASI symptom sub scores for erythema, thickness and scaling are rated as severe or very severe, and for the face, palm of a hand or sole of a foot the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

CONTINUATION – severe chronic plaque psoriasis, first-line biologic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ❍ Patient's PASI score has reduced by 75% or more (PASI 75) as compared to baseline PASI prior to commencing secukinumab

or

- ❍ Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab

or

- ❍ Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment

and

- ❍ The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value

or

- ❍ Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab

and

- ❍ Secukinumab to be administered at a maximum dose of 300 mg monthly

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Secukinumab *- continued*

INITIATION – ankylosing spondylitis, second-line biologic
Re-assessment required after 3 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis

and

- ○ The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept

or

- ○ Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis

CONTINUATION – ankylosing spondylitis, second-line biologic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Following 12 weeks initial treatment of secukinumab treatment, BASDAI has improved by 4 or more points from pre-secukinumab baseline on a 10 point scale, or by 50%, whichever is less

and

- ○ Physician considers that the patient has benefitted from treatment and that continued treatment is appropriate

and

- ○ Secukinumab to be administered at doses no greater than 300 mg monthly

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Secukinumab *- continued*

INITIATION – psoriatic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has had an initial Special Authority approval for adalimumab, etanercept or infliximab for psoriatic arthritis

and

- ○ Patient has experienced intolerable side effects from adalimumab, etanercept or infliximab

or

- ○ Patient has received insufficient benefit from adalimumab, etanercept or infliximab to meet the renewal criteria for adalimumab, etanercept or infliximab for psoriatic arthritis

or

- ○ Patient has had severe active psoriatic arthritis for six months duration or longer

and

- ○ Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose

and

- ○ Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses)

and

- ○ Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints

or

- ○ Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

- ○ Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application

or

- ○ Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour

or

- ○ ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

CONTINUATION – psoriatic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ○ The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior secukinumab treatment in the opinion of the treating physician

and

- ○ Secukinumab to be administered at doses no greater than 300 mg monthly

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Trastuzumab emtansine

INITIATION – early breast cancer

Prerequisites (tick boxes where appropriate)

- ○ Patient has early breast cancer expressing HER2 IHC3+ or ISH+

and

- ○ Documentation of pathological invasive residual disease in the breast and/or axiliary lymph nodes following completion of surgery

and

- ○ Patient has completed systemic neoadjuvant therapy with trastuzumab and chemotherapy prior to surgery

and

- ○ Disease has not progressed during neoadjuvant therapy

and

- ○ Patient has left ventricular ejection fraction of 45% or greater

and

- ○ Adjuvant treatment with trastuzumab emtansine to be commenced within 12 weeks of surgery

and

- ○ Trastuzumab emtansine to be discontinued at disease progression

and

- ○ Total adjuvant treatment duration must not exceed 42 weeks (14 cycles)

INITIATION – metastatic breast cancer

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ○ Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology)

and

- ○ Patient has previously received trastuzumab and chemotherapy, separately or in combination

and

- ○ The patient has received prior therapy for metastatic disease*

or

- ○ The patient developed disease recurrence during, or within six months of completing adjuvant therapy*

and

- ○ Patient has a good performance status (ECOG 0-1)

and

- ○ Patient does not have symptomatic brain metastases

or

- ○ Patient has brain metastases and has received prior local CNS therapy

and

- ○ Patient has not received prior funded trastuzumab emtansine or trastuzumab deruxtecan treatment

or

- ○ Patient has discontinued trastuzumab deruxtecan due to intolerance

and

- ○ The cancer did not progress while on trastuzumab deruxtecan

and

- ○ Treatment to be discontinued at disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Trastuzumab emtansine *- continued*

CONTINUATION – metastatic breast cancer
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

❍ The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine

and

❍ Treatment to be discontinued at disease progression

Note: *Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

I confirm that the above details are correct:

Signed: ..... Date: .....

RS2133 - Rituximab

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo)

INITIATION – haemophilia with inhibitors

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has mild congenital haemophilia complicated by inhibitors

or

- ○ Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy

or

- ○ Patient has acquired haemophilia

CONTINUATION – haemophilia with inhibitors

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient was previously treated with rituximab for haemophilia with inhibitors

and

- ○ An initial response lasting at least 12 months was demonstrated

and

- ○ Patient now requires repeat treatment

INITIATION – post-transplant

Prerequisites (tick boxes where appropriate)

- ○ The patient has B-cell post-transplant lymphoproliferative disorder*

and

- ○ To be used for a maximum of 8 treatment cycles

Note: Indications marked with * are unapproved indications.

CONTINUATION – post-transplant

Prerequisites (tick boxes where appropriate)

- ○ The patient has had a rituximab treatment-free interval of 12 months or more

and

- ○ The patient has B-cell post-transplant lymphoproliferative disorder*

and

- ○ To be used for no more than 6 treatment cycles

Note: Indications marked with * are unapproved indications.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

INITIATION – indolent, low-grade lymphomas or hairy cell leukaemia*
Re-assessment required after 9 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has indolent low grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy
- **and**
- ○ To be used for a maximum of 6 treatment cycles

or

- ○ The patient has indolent, low grade lymphoma or hairy cell leukaemia* requiring first-line systemic chemotherapy
- **and**
- ○ To be used for a maximum of 6 treatment cycles

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

CONTINUATION – indolent, low-grade lymphomas or hairy cell leukaemia*
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has had a rituximab treatment-free interval of 12 months or more
- **and**
- ○ The patient has indolent, low-grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy
- **and**
- ○ To be used for no more than 6 treatment cycles

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

INITIATION – aggressive CD20 positive NHL
Prerequisites (tick boxes where appropriate)

- ○ The patient has treatment naive aggressive CD20 positive NHL
- **and**
- ○ To be used with a multi-agent chemotherapy regimen given with curative intent
- **and**
- ○ To be used for a maximum of 8 treatment cycles

or

- ○ The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy
- **and**
- ○ To be used for a maximum of 6 treatment cycles

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

CONTINUATION – aggressive CD20 positive NHL

Prerequisites (tick boxes where appropriate)

- ○ The patient has had a rituximab treatment-free interval of 12 months or more

and

- ○ The patient has relapsed refractory/aggressive CD20 positive NHL

and

- ○ To be used with a multi-agent chemotherapy regimen given with curative intent

and

- ○ To be used for a maximum of 4 treatment cycles

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia.

INITIATION – Chronic lymphocytic leukaemia

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- ○ The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment

and

- ○ The patient is rituximab treatment naive

or

- ○ The patient is chemotherapy treatment naive

or

- ○ The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment

and

- ○ The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy

or

- ○ The patient's disease has relapsed and rituximab treatment is to be used in combination with funded venetoclax

and

- ○ The patient has good performance status

and

- ○ The patient does not have chromosome 17p deletion CLL

or

- ○ Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia

and

- ○ Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles

and

- ○ It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), bendamustine or venetoclax

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to < 2.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

CONTINUATION – Chronic lymphocytic leukaemia
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient's disease has relapsed and rituximab treatment is to be used in combination with funded venetoclax

or

- ○ The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL

and

- ○ The patient has had an interval of 36 months or more since commencement of initial rituximab treatment

and

- ○ The patient does not have chromosome 17p deletion CLL

and

- ○ It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustin

and

- ○ Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

INITIATION – severe cold haemagglutinin disease (CHAD)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has cold haemagglutinin disease*

and

- ○ Patient has severe disease which is characterized by symptomatic anaemia, transfusion dependence or disabling circulatory symptoms

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

CONTINUATION – severe cold haemagglutinin disease (CHAD)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned

or

- ○ Patient was previously treated with rituximab for severe cold haemagglutinin disease*

and

- ○ An initial response lasting at least 12 months was demonstrated

and

- ○ Patient now requires repeat treatment

Note: Indications marked with * are unapproved indications.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

INITIATION – warm autoimmune haemolytic anaemia (warm AIHA)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has warm autoimmune haemolytic anaemia*

and

- ○ One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to > 5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

CONTINUATION – warm autoimmune haemolytic anaemia (warm AIHA)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned

or

- ○ Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia*

and

- ○ An initial response lasting at least 12 months was demonstrated

and

- ○ Patient now requires repeat treatment

Note: Indications marked with * are unapproved indications.

INITIATION – immune thrombocytopenic purpura (ITP)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microlitre

or

- ○ Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding

and

- ○ Treatment with steroids and splenectomy have been ineffective

or

- ○ Treatment with steroids has been ineffective and splenectomy is an absolute contraindication

or

- ○ Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy)

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

CONTINUATION – immune thrombocytopenic purpura (ITP)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned

or

- ○ Patient was previously treated with rituximab for immune thrombocytopenic purpura*

and

- ○ An initial response lasting at least 12 months was demonstrated

and

- ○ Patient now requires repeat treatment

Note: Indications marked with * are unapproved indications.

INITIATION – thrombotic thrombocytopenic purpura (TTP)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks

and

- ○ Patient has thrombotic thrombocytopenic purpura* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange

or

- ○ Patient has acute idiopathic thrombotic thrombocytopenic purpura* with neurological or cardiovascular pathology

Note: Indications marked with * are unapproved indications.

CONTINUATION – thrombotic thrombocytopenic purpura (TTP)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura*

and

- ○ An initial response lasting at least 12 months was demonstrated

and

- ○ Patient now requires repeat treatment

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

INITIATION – pure red cell aplasia (PRCA)
Re-assessment required after 6 weeks
Prerequisites (tick box where appropriate)

- ❍ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ Patient has autoimmune pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder

Note: Indications marked with * are unapproved indications.

CONTINUATION – pure red cell aplasia (PRCA)
Re-assessment required after 6 weeks
Prerequisites (tick box where appropriate)

- ❍ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ Patient was previously treated with rituximab for pure red cell aplasia* associated with a demonstrable B-cell lymphoproliferative disorder and demonstrated an initial response lasting at least 12 months

Note: Indications marked with * are unapproved indications.

INITIATION – ANCA associated vasculitis
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ❍ Patient has been diagnosed with ANCA associated vasculitis*

and

- ❍ The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks

and

- ❍ Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months

or

- ❍ Patient has previously had a cumulative dose of cyclophosphamide > 15 g or a further repeat 3 month induction course of cyclophosphamide would result in a cumulative dose > 15 g

or

- ❍ Cyclophosphamide and methotrexate are contraindicated

or

- ❍ Patient is a female of child-bearing potential

or

- ❍ Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy

Note: Indications marked with * are unapproved indications.

CONTINUATION – ANCA associated vasculitis
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ❍ Patient has been diagnosed with ANCA associated vasculitis*

and

- ❍ Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis

and

- ❍ The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

INITIATION – treatment refractory systemic lupus erythematosus (SLE)

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or nephrologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has severe, immediately life- or organ-threatening SLE*

and

- ○ The disease has proved refractory to treatment with steroids at a dose of at least 1 mg/kg

and

- ○ The disease has relapsed following prior treatment for at least 6 months with maximal tolerated doses of azathioprine, mycophenolate mofetil and high dose cyclophosphamide, or cyclophosphamide is contraindicated

and

- ○ Maximum of four 1000 mg infusions of rituximab

Note: Indications marked with * are unapproved indications.

CONTINUATION – treatment refractory systemic lupus erythematosus (SLE)

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or nephrologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient's SLE* achieved at least a partial response to the previous round of prior rituximab treatment

and

- ○ The disease has subsequently relapsed

and

- ○ Maximum of two 1000 mg infusions of rituximab

Note: Indications marked with * are unapproved indications.

INITIATION – Antibody-mediated organ transplant rejection

Prerequisites (tick box where appropriate)

- ○ Patient has been diagnosed with antibody-mediated organ transplant rejection*

Note: Indications marked with * are unapproved indications.

INITIATION – ABO-incompatible organ transplant

Prerequisites (tick box where appropriate)

- ○ Patient is to undergo an ABO-incompatible solid organ transplant*

Note: Indications marked with * are unapproved indications.

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

INITIATION – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a nephrologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is a child with SDNS* or FRNS*

and

- ○ Treatment with steroids for at least a period of 3 months has been ineffective or associated with evidence of steroid toxicity

and

- ○ Treatment with ciclosporin for at least a period of 3 months has been ineffective and/or discontinued due to unacceptable side effects

and

- ○ Treatment with mycophenolate for at least a period of 3 months with no reduction in disease relapses

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with a * are unapproved indications.

CONTINUATION – Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a nephrologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient who was previously treated with rituximab for nephrotic syndrome*

and

- ○ Treatment with rituximab was previously successful and has demonstrated sustained response for > 6 months, but the condition has relapsed and the patient now requires repeat treatment

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with a * are unapproved indications.

INITIATION – Steroid resistant nephrotic syndrome (SRNS)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a nephrologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is a child with SRNS* where treatment with steroids and ciclosporin for at least 3 months have been ineffective

and

- ○ Treatment with tacrolimus for at least 3 months has been ineffective

and

- ○ Genetic causes of nephrotic syndrome have been excluded

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with a * are unapproved indications.

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

CONTINUATION – Steroid resistant nephrotic syndrome (SRNS)
Re-assessment required after 8 weeks
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a nephrologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient who was previously treated with rituximab for nephrotic syndrome*

and

- ○ Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with a * are unapproved indications.

INITIATION – Neuromyelitis Optica Spectrum Disorder (NMOSD)
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m2 administered weekly for four weeks

and

- ○ The patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms and clinical investigations supportive of a severe attack of NMOSD)

or

- ○ The patient has experienced a breakthrough attack of NMOSD

and

- ○ The patient is receiving treatment with mycophenolate

and

- ○ The patients is receiving treatment with corticosteroids

CONTINUATION – Neuromyelitis Optica Spectrum Disorder (NMOSD)
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m2 administered weekly for four weeks

and

- ○ The patients has responded to the most recent course of rituximab

and

- ○ The patient has not received rituximab in the previous 6 months

I confirm that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

INITIATION – Severe Refractory Myasthenia Gravis
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart

and

- ○ Treatment with corticosteroids and at least one other immunosuppressant for at least a period of 12 months has been ineffective

or

- ○ Treatment with at least one other immunosuppressant for a period of at least 12 months

and

- ○ Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects

CONTINUATION – Severe Refractory Myasthenia Gravis
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart

and

- ○ An initial response lasting at least 12 months was demonstrated

and

- ○ The patient has relapsed despite treatment with corticosteroids and at least one other immunosuppressant for a period of at least 12 months

or

- ○ The patient's myasthenia gravis has relapsed despite treatment with at least one immunosuppressant for a period of at least 12 months

and

- ○ Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects

INITIATION – Severe antisynthetase syndrome
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has confirmed antisynthetase syndrome

and

- ○ Patient has severe, immediately life or organ threatening disease, including interstitial lung disease

and

- ○ Treatment with at least 3 immunosuppressants (oral steroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has not be effective at controlling active disease

or

- ○ Rapid treatment is required due to life threatening complications

and

- ○ Maximum of four 1,000 mg infusions of rituximab

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Rixiмyo) - *continued*

CONTINUATION – Severe antisynthetase syndrome
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in inflammatory markers, muscle strength and pulmonary function

and

- ○ The patient has not received rituximab in the previous 6 months

and

- ○ Maximum of two cycles of 2 × 1,000 mg infusions of rituximab given two weeks apart

INITIATION – graft versus host disease
Prerequisites (tick boxes where appropriate)

- ○ Patient has refractory graft versus host disease following transplant

and

- ○ Treatment with at least 3 immunosuppressants (oral steroids, ciclosporin, tacrolimus, mycophenolate, sirolimus) has not be effective at controlling active disease

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

INITIATION – severe chronic inflammatory demyelinating polyneuropathy
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has severe chronic inflammatory demyelinating polyneuropathy (CIPD)

and

- ○ Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease

and

- ○ At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease

or

- ○ Rapid treatment is required due to life threatening complications

and

- ○ One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart

CONTINUATION – severe chronic inflammatory demyelinating polyneuropathy
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function compared to baseline

and

- ○ The patient has not received rituximab in the previous 6 months

and

- ○ One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Rixiimyo) - *continued*

INITIATION – anti-NMDA receptor autoimmune encephalitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has severe anti-NMDA receptor autoimmune encephalitis

and

- ○ Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease

and

- ○ At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease

or

- ○ Rapid treatment is required due to life threatening complications

and

- ○ One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart

CONTINUATION – anti-NMDA receptor autoimmune encephalitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function

and

- ○ The patient has not received rituximab in the previous 6 months

and

- ○ The patient has experienced a relapse and now requires further treatment

and

- ○ One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart

INITIATION – CD20+ low grade or follicular B-cell NHL
Re-assessment required after 9 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has CD20+ low grade or follicular B-cell NHL with relapsed disease following prior chemotherapy

and

- ○ To be used for a maximum of 6 treatment cycles

or

- ○ The patient has CD20+ low grade or follicular B-cell NHL requiring first-line systemic chemotherapy

and

- ○ To be used for a maximum of 6 treatment cycles

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

CONTINUATION – CD20+ low grade or follicular B-cell NHL
Re-assessment required after 24 months
Prerequisites (tick boxes where appropriate)

- ○ Rituximab is to be used for maintenance in CD20+ low grade or follicular B-cell NHL following induction with first-line systemic chemotherapy

and

- ○ Patient is intended to receive rituximab maintenance therapy for 2 years at a dose of 375 mg/m2 every 8 weeks (maximum of 12 cycles)

INITIATION – Membranous nephropathy
Re-assessment required after 6 weeks
Prerequisites (tick boxes where appropriate)

- ○ Patient has biopsy-proven primary/idiopathic membranous nephropathy*

or

- ○ Patient has PLA2 antibodies with no evidence of secondary cause, and an eGFR of > 60ml/min/1.73m2

and

- ○ Patient remains at high risk of progression to end-stage kidney disease despite more than 3 months of treatment with conservative measures (see Note)

and

- ○ The total rituximab dose would not exceed the equivalent of 375mg/m2 of body surface area per week for a total of 4 weeks

CONTINUATION – Membranous nephropathy
Re-assessment required after 6 weeks
Prerequisites (tick boxes where appropriate)

- ○ Patient was previously treated with rituximab for membranous nephropathy*

and

- ○ Treatment with rituximab was previously successful, but the condition has relapsed, and the patient now requires repeat treatment

or

- ○ Patient achieved partial response to treatment and requires repeat treatment (see Note)

and

- ○ The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks

Note:

a) Indications marked with * are unapproved indications.

b) High risk of progression to end-stage kidney disease defined as > 5g/day proteinuria.

c) Conservative measures include renin-angiotensin system blockade, blood-pressure management, dietary sodium and protein restriction, treatment of dyslipidaemia, and anticoagulation agents unless contraindicated or the patient has experienced intolerable side effects.

d) Partial response defined as a reduction of proteinuria of at least 50% from baseline, and between 0.3 grams and 3.5 grams per 24 hours.

I confirm that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

INITIATION – B-cell acute lymphoblastic leukaemia/lymphoma*
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Patient has newly diagnosed B-cell acute lymphoblastic leukaemia/lymphoma*

and

- ○ Treatment must be in combination with an intensive chemotherapy protocol with curative intent

and

- ○ The total rituximab dose would not exceed the equivalent of 375 mg/m2 per dose for a maximum of 18 doses

Note: Indications marked with * are unapproved indications.

INITIATION – desensitisation prior to transplant
Re-assessment required after 6 weeks
Prerequisites (tick boxes where appropriate)

- ○ Patient requires desensitisation prior to mismatched allogenic stem cell transplant*

and

- ○ Patient would receive no more than two doses at 375 mg/m2 of body-surface area

Note: Indications marked with * are unapproved indications.

INITIATION – pemiphigus*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist or relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has severe rapidly progressive pemphigus

and

- ○ Is used in combination with systemic corticosteroids (20 mg/day)

and

- ○ Skin involvement is at least 5% body surface area

or

- ○ Significant mucosal involvement (10 or more mucosal erosions) or diffuse gingivitis or confluent large erosions

or

- ○ Involvement of two or more mucosal sites

or

- ○ Patient has pemphigus

and

- ○ Patient has not experienced adequate clinical benefit from systemic corticosteroids (20 mg/day) in combination with a steroid sparing agent, unless contraindicated

Note: Indications marked with * are unapproved indications.

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Riximyo) - *continued*

CONTINUATION – pemiphigus*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist or relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has experienced adequate clinical benefit from rituximab treatment, with improvement in symptoms and healing of skin ulceration and reduction in corticosteroid requirement

and

- ○ Patient has not received rituximab in the previous 6 months

Note: Indications marked with * are unapproved indications.

INITIATION – immunoglobulin G4-related disease (IgG4-RD*)
Re-assessment required after 6 weeks
Prerequisites (tick boxes where appropriate)

- ○ Patient has confirmed diagnosis of IgG4-RD*

and

- ○ Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs for at least 3 months has been ineffective in lowering corticosteroid dose below 5 mg per day (prednisone equivalent) without relapse

or

- ○ Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs is contraindicated or associated with evidence of toxicity or intolerance

and

- ○ Total rituximab dose used should not exceed a maximum of two 1000 mg infusions of rituximab given two weeks apart

Note: Indications marked with * are unapproved indications.

CONTINUATION – immunoglobulin G4-related disease (IgG4-RD*)
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Treatment with rituximab for IgG4-RD* was previously successful and patient's disease has demonstrated sustained response, but the condition has relapsed

or

- ○ Patient is receiving maintenance treatment for IgG4-RD*

and

- ○ Rituximab re-treatment not to be given within 6 months of previous course of treatment

and

- ○ Maximum of two 1000 mg infusions of rituximab given two weeks apart

Note: Indications marked with * are unapproved indications.

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Mepolizumab

INITIATION – Severe eosinophilic asthma
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory physician or clinical immunologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient must be aged 12 years or older

and

- ○ Patient must have a diagnosis of severe eosinophilic asthma documented by a respiratory physician or clinical immunologist

and

- ○ Conditions that mimic asthma eg. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded

and

- ○ Patient has a blood eosinophil count of greater than 0.5 × 10^9 cells/L in the last 12 months

and

- ○ Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long acting beta-2 agonist, or budesonide/formoterol as part of the single maintenance and reliever therapy regimen, unless contraindicated or not tolerated

and

- ○ Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids

or

- ○ Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months

and

- ○ Treatment is not to be used in combination with subsidised benralizumab

and

- ○ Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment

and

- ○ Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma

or

- ○ Patient was refractory or intolerant to previous anti-IL5 biological therapy

and

- ○ Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment

CONTINUATION – Severe eosinophilic asthma
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory physician or clinical immunologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ An increase in the Asthma Control Test (ACT) score of at least 5 from baseline

and

- ○ Exacerbations have been reduced from baseline by 50% as a result of treatment with mepolizumab

or

- ○ Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Mepolizumab *- continued*

INITIATION – eosinophilic granulomatosis with polyangiitis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ❍ The patient has eosinophilic granulomatosis with polyangiitis

and

- ❍ The patient has trialled and not received adequate benefit from at least one of the following for at least three months (unless contraindicated to all): azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate, or rituximab

and

- ❍ The patient has trialled prednisone for a minimum of three months and is unable to maintain disease control at doses below 7.5 mg per day

or

- ❍ Corticosteroids are contraindicated

CONTINUATION – eosinophilic granulomatosis with polyangiitis
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ❍ Patient has no evidence of clinical disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

RS2063 - Adalimumab (Amgevita)

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita)

INITIATION – Behcet's disease - severe

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has severe Behcet's disease* that is significantly impacting the patient's quality of life

and

- ○ The patient has severe ocular, neurological, and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s)

or

- ○ The patient has severe gastrointestinal, rheumatological and/or mucocutaneous symptoms and has not responded adequately to two or more treatments appropriate for the particular symptom(s)

Note: Indications marked with * are unapproved indications.

INITIATION – Hidradenitis suppurativa

Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas

and

- ○ Patient has tried, but had an inadequate response to at least a 90 day trial of systemic antibiotics or patient has demonstrated intolerance to or has contraindications for systemic antibiotics

and

- ○ Patient has 3 or more active lesions

and

- ○ The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application

CONTINUATION – Hidradenitis suppurativa

Re-assessment required after 2 years

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline

and

- ○ The patient has a DLQI improvement of 4 or more from baseline

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Plaque psoriasis - severe chronic
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis

and

- ○ Patient has experienced intolerable side effects

or

- ○ Patient has received insufficient benefit to meet the renewal criteria for etanercept for severe chronic plaque psoriasis

or

- ○ Patient has "whole body" severe chronic plaque psoriasis with a (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis

or

- ○ Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis

or

- ○ Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10

and

- ○ Patient has tried, but had an inadequate response to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin

and

- ○ A PASI assessment or (DLQI) assessment has been completed for at least the most recent prior treatment course but no longer than 1 month following cessation of each prior treatment course and is no more than 1 month old at the time of application

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

CONTINUATION – Plaque psoriasis - severe chronic
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Patient had "whole body" severe chronic plaque psoriasis at the start of treatment
  and
  - ○ The patient has experienced a 75% or more reduction in PASI score, or is sustained at this level, when compared with the pre-treatment baseline value
    or
  - ○ The patient has a DLQI improvement of 5 or more, when compared with the pre-treatment baseline value

or

- ○ Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment
  and
  - ○ The patient has experienced a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values
    or
  - ○ The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value

or

- ○ Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment
  and
  - ○ The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value
    or
  - ○ Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing adalimumab

INITIATION – pyoderma gangrenosum
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has pyoderma gangrenosum*

and

- ○ Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and not received an adequate response

Note: Indications marked with * are unapproved indications.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Crohn's disease - adults
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has severe active Crohn's disease

and

- ○ Patient has a CDAI score of greater than or equal to 300 or HBI score of greater than or equal to 10

or

- ○ Patient has extensive small intestine disease affecting more than 50 cm of the small intestine

or

- ○ Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection

or

- ○ Patient has an ileostomy or colostomy and has intestinal inflammation

and

- ○ Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids

CONTINUATION – Crohn's disease - adults
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced 3 points, from when the patient was initiated on adalimumab

or

- ○ CDAI score is 150 or less, or HBI is 4 or less

or

- ○ The patient has demonstrated an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed

INITIATION – Crohn's disease - children
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Paediatric patient has active Crohn's disease

and

- ○ Patient has a PCDAI score of greater than or equal to 30

or

- ○ Patient has extensive small intestine disease

and

- ○ Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

CONTINUATION – Crohn's disease - children
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab

or

- ○ PCDAI score is 15 or less

or

- ○ The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed

INITIATION – Crohn's disease - fistulising
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has confirmed Crohn's disease

and

- ○ Patient has one or more complex externally draining enterocutaneous fistula(e)

or

- ○ Patient has one or more rectovaginal fistula(e)

or

- ○ Patient has complex peri-anal fistula

and

- ○ A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application

CONTINUATION – Crohn's disease - fistulising
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The number of open draining fistulae have decreased from baseline by at least 50%

or

- ○ There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Ocular inflammation - chronic
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation

or

- ○ Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss

and

- ○ Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective

or

- ○ Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose

or

- ○ Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate

CONTINUATION – Ocular inflammation - chronic
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had a good clinical response following 12 weeks' initial treatment

or

- ○ Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema)

or

- ○ Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Ocular inflammation - severe
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation

or

- ○ Patient has severe, vision-threatening ocular inflammation requiring rapid control

and

- ○ Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms

or

- ○ Patient developed new inflammatory symptoms while receiving high dose steroids

or

- ○ Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms

CONTINUATION – Ocular inflammation - severe
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had a good clinical response following 3 initial doses

or

- ○ Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema)

or

- ○ Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – ankylosing spondylitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

or

- ○ Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis

and

or

- ○ The patient has experienced intolerable side effects
- ○ The patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis

or

- ○ Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months

and

- ○ Patient has low back pain and stiffness that is relieved by exercise but not by rest

and

- ○ Patient has bilateral sacroiliitis demonstrated by radiology imaging

and

- ○ Patient has not responded adequately to treatment with two or more NSAIDs, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis

and

or

- ○ Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following BASMI measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right)
- ○ Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender

and

- ○ A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment and is no more than 1 month old at the time of application

CONTINUATION – ankylosing spondylitis
Re-assessment required after 2 years
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ For applications where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Arthritis - oligoarticular course juvenile idiopathic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA)

and

- ○ Patient has experienced intolerable side effects

or

- ○ Patient has received insufficient benefit to meet the renewal criteria for oligoarticular course JIA

or

- ○ To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- ○ Patient has had oligoarticular course JIA for 6 months duration or longer

and

- ○ At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

- ○ Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose)

CONTINUATION – Arthritis - oligoarticular course juvenile idiopathic
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline

or

- ○ On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Arthritis - polyarticular course juvenile idiopathic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA)

and

- ○ Patient has experienced intolerable side effects

or

- ○ Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA

or

- ○ To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- ○ Patient has had polyarticular course JIA for 6 months duration or longer

and

- ○ At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

- ○ Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

- ○ Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate

CONTINUATION – Arthritis - polyarticular course juvenile idiopathic
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline

or

- ○ On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Arthritis - psoriatic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

or

- ○ Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis

and

or

- ○ Patient has experienced intolerable side effects
- ○ Patient has received insufficient benefit to meet the renewal criteria for psoriatic arthritis

or

- ○ Patient has had active psoriatic arthritis for six months duration or longer

and

- ○ Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated)

and

- ○ Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated)

and

or

- ○ Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints
- ○ Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

or

or

- ○ Patient has CRP level greater than 15 mg/L measured no more than one month prior to the date of this application
- ○ Patient has an elevated ESR greater than 25 mm per hour
- ○ ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

CONTINUATION – Arthritis - psoriatic
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

or

- ○ Following initial treatment, the patient has at least a 50% decrease in swollen joint count from baseline and a clinically significant response in the opinion of the physician
- ○ Patient demonstrates at least a continuing 30% improvement in swollen joint count from baseline and a clinically significant response in the opinion of the treating physician

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Arthritis - rheumatoid
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis

and

- ○ The patient has experienced intolerable side effects

or

- ○ The patient has received insufficient benefit from etanercept to meet the renewal criteria for rheumatoid arthritis

or

- ○ Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer

and

- ○ Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- ○ Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated)

and

- ○ Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate at maximum tolerated doses (unless contraindicated)

and

- ○ Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin

or

- ○ Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate

and

- ○ Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints

or

- ○ Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

CONTINUATION – Arthritis - rheumatoid
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ○ On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Still's disease - adult-onset (AOSD)

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

or

- ○ The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for (AOSD)

and

or

- ○ Patient has experienced intolerable side effects from etanercept and/or tocilizumab
- ○ Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab

or

- ○ Patient diagnosed with AOSD according to the Yamaguchi criteria

and

- ○ Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, NSAIDs and methotrexate

and

- ○ Patient has persistent symptoms of disabling poorly controlled and active disease

INITIATION – ulcerative colitis

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has active ulcerative colitis

and

or

- ○ Patient's SCCAI score is greater than or equal to 4
- ○ Patient's PUCAI score is greater than or equal to 20

and

- ○ Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and systemic corticosteroids

and

- ○ Surgery (or further surgery) is considered to be clinically inappropriate

CONTINUATION – ulcerative colitis

Re-assessment required after 2 years

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

or

- ○ The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on biologic therapy
- ○ The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiated on biologic therapy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – undifferentiated spondyloarthiritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

- ○ Patient has tried and not responded to at least three months of each of methotrexate, sulphasalazine and leflunomide, at maximum tolerated doses (unless contraindicated)

and

- ○ Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application

or

- ○ Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application

or

- ○ ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

Note: Indications marked with * are unapproved indications.

CONTINUATION – undifferentiated spondyloarthiritis
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ○ The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response in the opinion of the treating physician

INITIATION – inflammatory bowel arthritis – axial
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has a diagnosis of active ulcerative colitis or active Crohn's disease

and

- ○ Patient has axial inflammatory pain for six months or more

and

- ○ Patient is unable to take NSAIDs

and

- ○ Patient has unequivocal sacroiliitis demonstrated by radiological imaging or MRI

and

- ○ Patient has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist

and

- ○ A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

CONTINUATION – inflammatory bowel arthritis – axial
Re-assessment required after 2 years
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less

INITIATION – inflammatory bowel arthritis – peripheral
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has a diagnosis of active ulcerative colitis or active Crohn's disease

and

- ○ Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular

and

- ○ Patient has tried and not experienced a response to at least three months of methotrexate, or azathioprine at a maximum tolerated dose (unless contraindicated)

and

- ○ Patient has tried and not experienced a response to at least three months of sulphasalazine at a maximum tolerated dose (unless contraindicated)

and

- ○ Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application

or

- ○ Patient has an ESR greater than 25 mm per hour

or

- ○ ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

CONTINUATION – inflammatory bowel arthritis – peripheral
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ○ Patient demonstrates at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Palivizumab

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ❍ Palivizumab to be administered during the annual RSV season

and

- ❍ Infant was born in the last 12 months

and

- ❍ Infant was born at less than 32 weeks zero days' gestation

or

- ❍ Child was born in the last 24 months

and

- ❍ Child has severe lung, airway, neurological or neuromuscular disease that requires ongoing ventilatory/respiratory support (see Note A) in the community

or

- ❍ Child has haemodynamically significant heart disease

and

- ❍ Child has unoperated simple congenital heart disease with significant left to right shunt (see Note B)

or

- ❍ Child has unoperated or surgically palliated complex congenital heart disease

or

- ❍ Child has severe pulmonary hypertension (see Note C)

or

- ❍ Child has moderate or severe left ventricular (LV) failure (see Note D)

or

- ❍ Child has severe combined immune deficiency, confirmed by an immunologist, but has not received a stem cell transplant

or

- ❍ Child has inborn errors of immunity (see Note E) that increase susceptibility to life-threatening viral respiratory infections, confirmed by an immunologist

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Palivizumab *- continued*

CONTINUATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ❍ Palivizumab to be administered during the annual RSV season

and

- ❍ Child was born in the last 24 months

and

- ❍ Child has severe lung, airway, neurological or neuromuscular disease that requires ongoing ventilatory/respiratory support (see Note A) in the community

or

- ❍ Child has haemodynamically significant heart disease

and

- ❍ Child has unoperated simple congenital heart disease with significant left to right shunt (see Note B)

or

- ❍ Child has unoperated or surgically palliated complex congenital heart disease

or

- ❍ Child has severe pulmonary hypertension (see Note C)

or

- ❍ Child has moderate or severe left ventricular (LV) failure (see Note D)

or

- ❍ Child has severe combined immune deficiency, confirmed by an immunologist, but has not received a stem cell transplant

or

- ❍ Child has inborn errors of immunity (see Note E) that increase susceptibility to life-threatening viral respiratory infections, confirmed by an immunologist

Note:

a) Ventilatory/respiratory support includes those on home oxygen, CPAP/VPAP and those with tracheostomies in situ managed at home

b) Child requires/will require heart failure medication, and/or child has significant pulmonary hypertension, and/or infant will require surgical palliation/definitive repair within the next 3 months

c) Mean pulmonary artery pressure more than 25 mmHg

d) LV Ejection Fraction less than 40%

e) Inborn errors of immunity include, but are not limited to, IFNAR deficiencies

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Gemtuzumab ozogamicin

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient has not received prior chemotherapy for this condition

and

- ○ Patient has de novo CD33-positive acute myeloid leukaemia

and

- ○ Patient does not have acute promyelocytic leukaemia

and

- ○ Gemtuzumab ozogamicin will be used in combination with standard anthracycline and cytarabine (AraC)

and

- ○ Patient is being treated with curative intent

and

- ○ Patient's disease risk has been assessed by cytogenetic testing to be good or intermediate

and

- ○ Patient must be considered eligible for standard intensive remission induction chemotherapy with standard anthracycline and cytarabine (AraC)

and

- ○ Gemtuzumab ozogamicin to be funded for one course only (one dose at 3 mg per m^2 body surface area or up to 2 vials of 5 mg as separate doses)

Note: Acute myeloid leukaemia excludes acute promyelocytic leukaemia and acute myeloid leukaemia that is secondary to another haematological disorder (eg myelodysplasia or myeloproliferative disorder).

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Benralizumab

INITIATION – Severe eosinophilic asthma
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory physician or clinical immunologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient must be aged 12 years or older

and

- ○ Patient must have a diagnosis of severe eosinophilic asthma documented by a respiratory physician or clinical immunologist

and

- ○ Conditions that mimic asthma eg. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded

and

- ○ Patient has a blood eosinophil count of greater than 0.5 × 10^9 cells/L in the last 12 months

and

- ○ Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long-acting beta-2 agonist, or budesonide/formoterol as part of the anti-inflammatory reliever therapy plus maintenance regimen, unless contraindicated or not tolerated

and

- ○ Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids

or

- ○ Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months

and

- ○ Treatment is not to be used in combination with subsidised mepolizumab

and

- ○ Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment

and

- ○ Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma

or

- ○ Patient was refractory or intolerant to previous anti-IL5 biological therapy

and

- ○ Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment

CONTINUATION – Severe eosinophilic asthma
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory physician or clinical immunologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ An increase in the Asthma Control Test (ACT) score of at least 5 from baseline

and

- ○ Exacerbations have been reduced from baseline by 50% as a result of treatment with benralizumab

or

- ○ Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ustekinumab

INITIATION – Crohn's disease - adults
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment

or

- ○ Patient has active Crohn's disease

and

- ○ Patient has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

- ○ Patient meets the initiation criteria for prior biologic therapies for Crohn's disease

and

- ○ Other biologics for Crohn's disease are contraindicated

CONTINUATION – Crohn's disease - adults
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated on biologic therapy

or

- ○ CDAI score is 150 or less, or HBI is 4 or less

or

- ○ The patient has experienced an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed

and

- ○ Ustekinumab to be administered at a dose no greater than 90 mg every 8 weeks

INITIATION – Crohn's disease - children*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment

or

- ○ Patient has active Crohn's disease

and

- ○ Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

- ○ Patient meets the initiation criteria for prior biologic therapies for Crohn's disease

and

- ○ Other biologics for Crohn's disease are contraindicated

Note: Indication marked with * is an unapproved indication.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ustekinumab *- continued*

CONTINUATION – Crohn's disease - children*
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy
- **or**
- ○ PCDAI score is 15 or less
- **or**
- ○ The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed

and

- ○ Ustekinumab to administered at a dose no greater than 90 mg every 8 weeks

Note: Indication marked with * is an unapproved indication.

INITIATION – ulcerative colitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment

or

- ○ Patient has active ulcerative colitis

and

- ○ Patient has had an initial approval for prior biologic therapy for ulcerative colitis and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

- ○ Patient meets the initiation criteria for prior biologic therapies for ulcerative colitis

and

- ○ Other biologics for ulcerative colitis are contraindicated

CONTINUATION – ulcerative colitis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy
- **or**
- ○ PUCAI score has reduced by 10 points or more from the PUCAI score since initiation on biologic therapy*

and

- ○ Ustekinumab will be used at a dose no greater than 90 mg intravenously every 8 weeks

Note: Criterion marked with * is for an unapproved indication.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Vedolizumab

INITIATION – Crohn's disease - adults
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has active Crohn's disease

and

- ○ Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated)

or

- ○ Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10

or

- ○ Patient has extensive small intestine disease affecting more than 50 cm of the small intestine

or

- ○ Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection

or

- ○ Patient has an ileostomy or colostomy, and has intestinal inflammation

and

- ○ Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids

or

- ○ Patient has experienced intolerable side effects from immunomodulators and corticosteroids

or

- ○ Immunomodulators and corticosteroids are contraindicated

CONTINUATION – Crohn's disease - adults
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated on biologic therapy

or

- ○ CDAI score is 150 or less, or HBI is 4 or less

or

- ○ The patient has experienced an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed

and

- ○ Vedolizumab to administered at a dose no greater than 300 mg every 8 weeks

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Vedolizumab *- continued*

INITIATION – Crohn's disease - children*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Paediatric patient has active Crohn's disease

and

- ○ Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated)

or

- ○ Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30

or

- ○ Patient has extensive small intestine disease

and

- ○ Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids

or

- ○ Patient has experienced intolerable side effects from immunomodulators and corticosteroids

or

- ○ Immunomodulators and corticosteroids are contraindicated

Note: Indication marked with * is an unapproved indication.

CONTINUATION – Crohn's disease - children*
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy

or

- ○ PCDAI score is 15 or less

or

- ○ The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed

and

- ○ Vedolizumab to administered at a dose no greater than 300mg every 8 weeks

Note: Indication marked with * is an unapproved indication.

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Vedolizumab *- continued*

INITIATION – ulcerative colitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ❍ Patient has active ulcerative colitis

and

- ❍ Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated)

or

- ❍ Patient has a SCCAI score is greater than or equal to 4

or

- ❍ Patient's PUCAI score is greater than or equal to 20*

and

- ❍ Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids

or

- ❍ Patient has experienced intolerable side effects from immunomodulators and corticosteroids

or

- ❍ Immunomodulators and corticosteroids are contraindicated

Note: Indication marked with * is an unapproved indication.

CONTINUATION – ulcerative colitis
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ❍ The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy

or

- ❍ The PUCAI score has reduced by 10 points or more from the PUCAI score since initiation on biologic therapy *

and

- ❍ Vedolizumab will be used at a dose no greater than 300 mg intravenously every 8 weeks

Note: Indication marked with * is an unapproved indication.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Brentuximab

INITIATION – relapsed/refractory Hodgkin lymphoma
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has relapsed/refractory CD30-positive Hodgkin lymphoma after two or more lines of chemotherapy
- **and**
- ○ Patient is ineligible for autologous stem cell transplant

or

- ○ Patient has relapsed/refractory CD30-positive Hodgkin lymphoma
- **and**
- ○ Patient has previously undergone autologous stem cell transplant

and
○ Patient has not previously received funded brentuximab vedotin
and
○ Response to brentuximab vedotin treatment is to be reviewed after a maximum of 6 treatment cycles
and
○ Brentuximab vedotin to be administered at doses no greater than 1.8 mg/kg every 3 weeks

CONTINUATION – relapsed/refractory Hodgkin lymphoma
Re-assessment required after 9 months
Prerequisites (tick boxes where appropriate)

○ Patient has achieved a partial or complete response to brentuximab vedotin after 6 treatment cycles
and
○ Treatment remains clinically appropriate and the patient is benefitting from treatment and treatment is being tolerated
and
○ Patient is to receive a maximum of 16 total cycles of brentuximab vedotin treatment

INITIATION – anaplastic large cell lymphoma
Re-assessment required after 9 months
Prerequisites (tick boxes where appropriate)

○ Patient has relapsed/refractory CD30-positive systemic anaplastic large cell lymphoma
and
○ Patient has an ECOG performance status of 0-1
and
○ Patient has not previously received brentuximab vedotin
and
○ Response to brentuximab vedotin treatment is to be reviewed after a maximum of 6 treatment cycles
and
○ Brentuximab vedotin to be administered at doses no greater than 1.8 mg/kg every 3 weeks

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Brentuximab *- continued*

CONTINUATION – anaplastic large cell lymphoma
Re-assessment required after 9 months
Prerequisites (tick boxes where appropriate)

- ❍ Patient has achieved a partial or complete response to brentuximab vedotin after 6 treatment cycles

and

- ❍ Treatment remains clinically appropriate and the patient is benefitting from treatment and treatment is being tolerated

and

- ❍ Patient is to receive a maximum of 16 total cycles of brentuximab vedotin treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Trastuzumab (Herzuma)

INITIATION – early breast cancer
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has early breast cancer expressing HER-2 IHC 3+ or ISH + (including FISH or other current technology

and

- ○ Maximum cumulative dose of 106 mg/kg (12 months' treatment)

CONTINUATION – early breast cancer*
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology

and

- ○ The patient received prior adjuvant trastuzumab treatment for early breast cancer

and

- ○ The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer

or

- ○ The patient discontinued lapatinib within 3 months due to intolerable side effects and the cancer did not progress whilst on lapatinib

or

- ○ He cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab

and

- ○ Trastuzumab will not be given in combination with pertuzumab

or

- ○ Trastuzumab to be administered in combination with pertuzumab

and

- ○ Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer

and

- ○ The patient has good performance status (ECOG grade 0-1)

and

- ○ Trastuzumab to be discontinued at disease progression

or

- ○ Patient has previously discontinued treatment with trastuzumab in the metastatic setting for reasons other than severe toxicity or disease progression

and

- ○ Patient has signs of disease progression

and

- ○ Disease has not progressed during previous treatment with trastuzumab

Note: * For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Trastuzumab (Herzuma) *- continued*

INITIATION – metastatic breast cancer
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology)

and

- ○ The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer

or

- ○ The patient discontinued lapatinib within 3 months due to intolerable side effects and the cancer did not progress whilst on lapatinib

and

- ○ Trastuzumab will not be given in combination with pertuzumab

or

- ○ Trastuzumab to be administered in combination with pertuzumab

and

- ○ Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer

and

- ○ The patient has good performance status (ECOG grade 0-1)

and

- ○ Trastuzumab to be discontinued at disease progression

CONTINUATION – metastatic breast cancer
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology)

and

- ○ The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab

and

- ○ Trastuzumab to be discontinued at disease progression

or

- ○ Patient has previously discontinued treatment with trastuzumab for reasons other than severe toxicity or disease progression

and

- ○ Patient has signs of disease progression

and

- ○ Disease has not progressed during previous treatment with trastuzumab

INITIATION – gastric, gastro-oesophageal junction and oesophageal cancer
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has locally advanced or metastatic gastric, gastro-oesophageal junction or oesophageal cancer expressing HER-2 IHC 2+ FISH+ or IHC3+ (or other current technology)

and

- ○ Patient has an ECOG score of 0-2

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Trastuzumab (Herzuma) *- continued*

CONTINUATION – gastric, gastro-oesophageal junction and oesophageal cancer
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ❍ The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab

and

- ❍ Trastuzumab to be discontinued at disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Trastuzumab deruxtecan

INITIATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has metastatic breast cancer expressing HER-2 IHC3+ or ISH+ (including FISH or other current technology)

and

- ○ Patient has previously received trastuzumab and chemotherapy, separately or in combination

and

- ○ The patient has received prior therapy for metastatic disease

or

- ○ The patient developed disease recurrence during, or within six months of completing adjuvant therapy

and

- ○ Patient has a good performance status (ECOG 0-1)

and

- ○ Patient has not received prior funded trastuzumab deruxtecan treatment

and

- ○ Treatment to be discontinued at disease progression

CONTINUATION
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab deruxtecan

and

- ○ Treatment to be discontinued at disease progression

Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Bevacizumab

INITIATION – unresectable hepatocellular carcinoma
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient is currently on treatment with bevacizumab, and met all remaining criteria prior to commencing treatment

or

- ○ Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma

and

- ○ Patient has preserved liver function (Child-Pugh A)

and

- ○ Transarterial chemoembolisation (TACE) is unsuitable

and

- ○ Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma

or

- ○ Patient received funded lenvatinib before 1 March 2025

or

- ○ Patient has experienced treatment-limiting toxicity from treatment with lenvatinib

and

- ○ No disease progression since initiation of lenvatinib

and

- ○ Patient has an ECOG performance status of 0-2

and

- ○ To be given in combination with atezolizumab

CONTINUATION – unresectable hepatocellular carcinoma
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ No evidence of disease progression

INITIATION – advanced or metastatic ovarian cancer
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has FIGO Stage IV epithelial ovarian, fallopian tube, or primary peritoneal cancer

or

- ○ The patient has previously untreated advanced (FIGO Stage IIIB or IIIC) epithelial ovarian, fallopian tube, or primary peritoneal cancer

and

- ○ Debulking surgery is inappropriate

or

- ○ The cancer is sub-optimally debulked (maximum diameter of any gross residual disease greater than 1cm)

and

- ○ Bevacizumab to be administered at a maximum dose of 15 mg/kg every three weeks

and

- ○ 18 weeks concurrent treatment with chemotherapy is planned

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Bevacizumab *- continued*

CONTINUATION – advanced or metastatic ovarian cancer
Re-assessment required after 4 months
Prerequisites (tick box where appropriate)

- ○ No evidence of disease progression

INITIATION – Recurrent Respiratory Papillomatosis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Maximum of 6 doses

and

- ○ The patient has recurrent respiratory papillomatosis

and

- ○ The treatment is for intra-lesional administration

CONTINUATION – Recurrent Respiratory Papillomatosis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Maximum of 6 doses

and

- ○ The treatment is for intra-lesional administration

and

- ○ There has been a reduction in surgical treatments or disease regrowth as a result of treatment

INITIATION – Ocular Conditions
Prerequisites (tick boxes where appropriate)

- ○ Ocular neovascularisation

or

- ○ Exudative ocular angiopathy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Inotuzumab ozogamicin

INITIATION
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has relapsed or refractory CD22-positive B-cell acute lymphoblastic leukaemia/lymphoma, including minimal residual disease

and

- ○ Patient has ECOG performance status of 0-2

and

- ○ Patient has Philadelphia chromosome positive B-Cell ALL

  and

  ○ Patient has previously received a tyrosine kinase inhibitor

  or

- ○ Patient has received one prior line of treatment involving intensive chemotherapy

and

- ○ Treatment is to be administered for a maximum of 3 cycles

CONTINUATION
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Patient is not proceeding to a stem cell transplant

and

- ○ Patient has experienced complete disease response

  or

  ○ Patient has experienced complete remission with incomplete haematological recovery

and

- ○ Treatment with inotuzumab ozogamicin is to cease after a total duration of 6 cycles

I confirm that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Basiliximab

INITIATION

Prerequisites (tick box where appropriate)

○ For use in solid organ transplants

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Mabthera)

INITIATION – rheumatoid arthritis - prior TNF inhibitor use
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had an initial community Special Authority approval for at least one of etanercept and/or adalimumab for rheumatoid arthritis

and

- ○ The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept

or

- ○ Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for rheumatoid arthritis

and

- ○ Rituximab to be used as an adjunct to methotrexate or leflunomide therapy

or

- ○ Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used

and

- ○ Maximum of two 1,000 mg infusions of rituximab given two weeks apart

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Mabthera) - *continued*

INITIATION – rheumatoid arthritis - TNF inhibitors contraindicated
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Treatment with a Tumour Necrosis Factor alpha inhibitor is contraindicated

and

- ○ Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer

and

- ○ Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose

and

- ○ Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses)

and

- ○ Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of cyclosporin

or

- ○ Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold

or

- ○ Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate

and

- ○ Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints

or

- ○ Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

- ○ Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application

or

- ○ C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

and

- ○ Rituximab to be used as an adjunct to methotrexate or leflunomide therapy

or

- ○ Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used

and

- ○ Maximum of two 1,000 mg infusions of rituximab given two weeks apart

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rituximab (Mabthera) - *continued*

CONTINUATION – rheumatoid arthritis - re-treatment in 'partial responders' to rituximab
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ At 4 months following the initial course of rituximab infusions the patient had between a 30% and 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ○ At 4 months following the second course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ○ At 4 months following the third and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

and

- ○ Rituximab re-treatment not to be given within 6 months of the previous course of treatment

and

- ○ Rituximab to be used as an adjunct to methotrexate or leflunomide therapy

or

- ○ Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used

and

- ○ Maximum of two 1,000 mg infusions of rituximab given two weeks apart

CONTINUATION – rheumatoid arthritis - re-treatment in 'responders' to rituximab
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ At 4 months following the initial course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

- ○ At 4 months following the second and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

and

- ○ Rituximab re-treatment not to be given within 6 months of the previous course of treatment

and

- ○ Rituximab to be used as an adjunct to methotrexate or leflunomide therapy

or

- ○ Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used

and

- ○ Maximum of two 1,000 mg infusions of rituximab given two weeks apart

I confirm that the above details are correct:

Signed: ..... Date: .....

RS1922 - Adalimumab (Humira - Alternative brand)

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Humira - Alternative brand)

INITIATION – Behcet's disease – severe
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

- ○ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

- ○ Patient has received a maximum of 6 months treatment with Amgevita

and

- ○ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

CONTINUATION – Behcet's disease – severe
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had a good clinical response to treatment with measurably improved quality of life

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

INITIATION – Hidradenitis suppurativa
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist or Practitioner on the recommendation of a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

- ○ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

- ○ Patient has received a maximum of 6 months treatment with Amgevita

and

- ○ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 7 days. Fortnightly dosing has been considered

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Humira - Alternative brand) *- continued*

CONTINUATION – Hidradenitis suppurativa
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ❍ Prescribed by, or recommended by a dermatologist or Practitioner on the recommendation of a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline

and

- ❍ The patient has a Dermatology Quality of Life Index improvement of 4 or more from baseline

and

- ❍ Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered

INITIATION – Psoriasis - severe chronic plaque
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ❍ Prescribed by, or recommended by a dermatologist or Practitioner on the recommendation of a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

- ❍ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

- ❍ Patient has received a maximum of 6 months treatment with Amgevita

and

- ❍ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- ❍ Adalimumab to be administered at doses no greater than 40 mg every 14 days

I confirm that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Humira - Alternative brand) *- continued*

CONTINUATION – Psoriasis - severe chronic plaque
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist or Practitioner on the recommendation of a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient had "whole body" severe chronic plaque psoriasis at the start of treatment

and

- ○ Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value

or

- ○ Following each prior adalimumab treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value

or

- ○ Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment

and

- ○ Following each prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values

or

- ○ Following each prior adalimumab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

INITIATION – Pyoderma gangrenosum
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

- ○ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

- ○ Patient has received a maximum of 6 months treatment with Amgevita

and

- ○ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- ○ A maximum of 8 doses

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Humira - Alternative brand) *- continued*

CONTINUATION – Pyoderma gangrenosum
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has demonstrated clinical improvement and continues to require treatment

and

- ○ A maximum of 8 doses

INITIATION – Crohn's disease - adult
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a gastroenterologist or Practitioner on the recommendation of a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita

or

- ○ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen

or

- ○ Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment

and

- ○ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

CONTINUATION – Crohn's disease - adult
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a gastroenterologist or Practitioner on the recommendation of a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab

or

- ○ CDAI score is 150 or less

or

- ○ The patient has demonstrated an adequate response to treatment, but CDAI score cannot be assessed

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Humira - Alternative brand) *- continued*

INITIATION – Crohn's disease - children
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a gastroenterologist or Practitioner on the recommendation of a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita

or

- ○ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen

or

- ○ Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment

and

- ○ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

CONTINUATION – Crohn's disease - children
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a gastroenterologist or Practitioner on the recommendation of a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab

or

- ○ PCDAI score is 15 or less

or

- ○ The patient has demonstrated an adequate response to treatment, but PCDAI score cannot be assessed

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

INITIATION – Crohn's disease - fistulising
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a gastroenterologist or Practitioner on the recommendation of a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita

or

- ○ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen

or

- ○ Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment

and

- ○ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Humira - Alternative brand) *- continued*

CONTINUATION – Crohn's disease - fistulising
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a gastroenterologist or Practitioner on the recommendation of a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The number of open draining fistulae have decreased from baseline by at least 50%

or

- ○ There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

INITIATION – Ocular inflammation – chronic
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita

or

- ○ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen

or

- ○ Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment

and

- ○ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

CONTINUATION – Ocular inflammation – chronic
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has had a good clinical response following 12 weeks' initial treatment

or

- ○ Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema)

or

- ○ Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Humira - Alternative brand) *- continued*

INITIATION – Ocular inflammation – severe
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita

or

❍ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen

or

❍ Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment

and

❍ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

❍ Adalimumab to be administered at doses no greater than 40 mg every 14 days

CONTINUATION – Ocular inflammation – severe
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ The patient has had a good clinical response following 3 initial doses

or

❍ Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema)

or

❍ Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old

and

❍ Adalimumab to be administered at doses no greater than 40 mg every 14 days

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Humira - Alternative brand) *- continued*

INITIATION – ankylosing spondylitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

- ○ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita)

and

- ○ Patient has received a maximum of 6 months treatment with Amgevita

and

- ○ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

CONTINUATION – ankylosing spondylitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

INITIATION – Arthritis – oligoarticular course juvenile idiopathic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

- ○ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

- ○ Patient has received a maximum of 6 months treatment with Amgevita

and

- ○ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Humira - Alternative brand) *- continued*

CONTINUATION – Arthritis – oligoarticular course juvenile idiopathic
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ For patients that demonstrate at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

INITIATION – Arthritis - polyarticular course juvenile idiopathic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

- ○ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

- ○ Patient has received a maximum of 6 months treatment with Amgevita

and

- ○ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

CONTINUATION – Arthritis - polyarticular course juvenile idiopathic
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ For patients that demonstrate at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

INITIATION – Arthritis - psoriatic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

- ○ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

- ○ Patient has received a maximum of 6 months treatment with Amgevita

and

- ○ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Humira - Alternative brand) *- continued*

CONTINUATION – Arthritis - psoriatic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

INITIATION – Arthritis – rheumatoid
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

- ○ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

- ○ Patient has received a maximum of 6 months treatment with Amgevita

and

- ○ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

or

- ○ Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response

CONTINUATION – Arthritis – rheumatoid
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician

and

- ○ Adalimumab to be administered at doses no greater than 40 mg every 14 days

or

- ○ Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Humira - Alternative brand) *- continued*

INITIATION – Still's disease – adult-onset (AOSD)
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ❍ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

or

- ❍ Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen

and

- ❍ Patient has received a maximum of 6 months treatment with Amgevita

and

- ❍ Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

CONTINUATION – Still's disease – adult-onset (AOSD)
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ❍ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ The patient has demonstrated a sustained improvement in inflammatory markers and functional status

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Abciximab

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For use in patients with acute coronary syndromes undergoing percutaneous coronary intervention

or

- ○ For use in patients undergoing intra-cranial intervention

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nivolumab

INITIATION – unresectable or metastatic melanoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

and

- ○ The individual has ECOG performance 0-2

and

- ○ The individual has not received funded pembrolizumab

or

- ○ The individual has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance

and

- ○ The cancer did not progress while the individual was on pembrolizumab

and

- ○ The individual has been diagnosed in the metastatic or unresectable stage III or IV setting

or

- ○ The individual did not receive treatment in the perioperative setting with a PD-1/PD-L1 inhibitor

or

- ○ The individual received treatment in the perioperative setting with a PD-1/PD-L1 inhibitor

and

- ○ The individual did not experience disease recurrence while on treatment with that PD-1/PD-L1 inhibitor

and

- ○ The individual did not experience disease recurrence within six months of completing perioperative treatment with a PD-1/PD-L1 inhibitor

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nivolumab *- continued*

CONTINUATION – unresectable or metastatic melanoma, less than 24 months on treatment
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual's disease has had a complete response to treatment
  or
- ○ The individual's disease has had a partial response to treatment
  or
- ○ The individual has stable disease

and

- ○ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

or

- ○ The individual has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression

and

- ○ The individual has signs of disease progression

and

- ○ Disease has not progressed during previous treatment with nivolumab

CONTINUATION – unresectable or metastatic melanoma, more than 24 months on treatment
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual has been on treatment for more than 24 months

and

- ○ The individual's disease has had a complete response to treatment
  or
- ○ The individual's disease has had a partial response to treatment
  or
- ○ The individual has stable disease

and

- ○ Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period

or

- ○ The individual has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression

and

- ○ The individual has signs of disease progression

and

- ○ Disease has not progressed during previous treatment with nivolumab

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nivolumab *- continued*

INITIATION – renal cell carcinoma, first line
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Patient is currently on treatment with nivolumab and met all remaining criteria prior to commencing treatment

or

- ○ The patient has metastatic renal cell carcinoma

and

- ○ The patient is treatment naive

and

- ○ The patient has ECOG performance status 0-2

and

- ○ The disease is predominantly of clear cell histology

and

- ○ The patient has sarcomatoid histology

or

- ○ Haemoglobin levels less than the lower limit of normal

or

- ○ Corrected serum calcium level greater than 10 mg/dL (2.5 mmol/L)

or

- ○ Neutrophils greater than the upper limit of normal

or

- ○ Platelets greater than the upper limit of normal

or

- ○ Interval of less than 1 year from original diagnosis to the start of systemic therapy

or

- ○ Karnofsky performance score of less than or equal to 70

and

- ○ Nivolumab is to be used in combination with ipilimumab for the first four treatment cycles at a maximum dose of 3 mg/kg

and

- ○ Nivolumab is to be used at a maximum maintenance dose of 240 mg every 2 weeks (or equivalent)

INITIATION – renal cell carcinoma, second line
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has metastatic renal-cell carcinoma

and

- ○ The disease is of predominant clear-cell histology

and

- ○ Patient has ECOG performance status 0-2

and

- ○ Patient has documented disease progression following one or two previous regimens of antiangiogenic therapy

and

- ○ Patient has not previously received a funded immune checkpoint inhibitor

and

- ○ Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nivolumab *- continued*

CONTINUATION – renal cell carcinoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Patient's disease has had a complete response to treatment
  or
- ○ Patient's disease has had a partial response to treatment
  or
- ○ Patient has stable disease

and

- ○ No evidence of disease progression

and

- ○ Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

RS2134 - Pembrolizumab

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab

INITIATION – stage III or IV resectable melanoma - neoadjuvant
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment

or

- ○ The individual has resectable stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note)

and

- ○ The individual has not received prior funded systemic treatment in the perioperative setting for their stage IIIB, IIIC, IIID or IV melanoma

and

- ○ Treatment must be prior to complete surgical resection

and

- ○ Pembrolizumab must be administered as monotherapy

and

- ○ The individual has ECOG performance score 0-2

and

- ○ Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

CONTINUATION – stage III or IV resectable melanoma - neoadjuvant
Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ The individual has received neoadjuvant treatment with an immune checkpoint inhibitor

and

❍ The individual meets initiation criteria for pembrolizumab for stage III or IV resected melanoma – adjuvant

or

❍ The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor

and

❍ The individual meets continuation criteria for pembrolizumab for stage III or IV resected melanoma – adjuvant

or

❍ The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor

and

❍ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV

and

❍ The individual meets initiation criteria for pembrolizumab for unresectable or metastatic melanoma

or

❍ The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor

and

❍ The individual has received treatment with an immune checkpoint inhibitor for unresectable or metastatic melanoma

and

❍ The individual meets continuation criteria for pembrolizumab for unresectable or metastatic melanoma

Note:

a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition

b) Initiating treatment within 13 weeks of complete surgical resection means either 13 weeks after resection (primary or lymphadenectomy) or 13 weeks prior to the scheduled date of the resection (primary or lymphadenectomy)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

INITIATION – stage III or IV resected melanoma - adjuvant
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment

or

- ○ The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a)

and

- ○ Adjuvant treatment with pembrolizumab is required

and

- ○ The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma

and

- ○ Treatment must be in addition to complete surgical resection

and

- ○ Treatment must be initiated within 13 weeks of complete surgical resection, unless delay is necessary due to post-surgery recovery (see note b)

and

- ○ Pembrolizumab must be administered as monotherapy

and

- ○ The individual has ECOG performance score 0-2

and

- ○ Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent)

Note:

a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition

b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

CONTINUATION – stage III or IV resected melanoma - adjuvant
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ No evidence of disease recurrence

and

- ○ Pembrolizumab must be administered as monotherapy

and

- ○ Pembrolizumab to be administered at a fixed dose of 200 mg every three weeks (or equivalent) for a maximum of 12 months total treatment course, including any systemic neoadjuvant treatment

and

- ○ Treatment to be discontinued at signs of disease recurrence or at completion of 12 months total treatment course (equivalent to 18 cycles at a dose of 200 mg every 3 weeks), including any systemic neoadjuvant treatment

or

- ○ The individual has received adjuvant treatment with an immune checkpoint inhibitor

and

- ○ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV

and

- ○ The individual meets initiation criteria for pembrolizumab for unresectable or metastatic melanoma

or

- ○ The individual has received adjuvant treatment with an immune checkpoint inhibitor

and

- ○ The individual has received treatment with an immune checkpoint inhibitor for unresectable or metastatic melanoma

and

- ○ The individual meets continuation criteria for pembrolizumab for unresectable or metastatic melanoma

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

INITIATION – unresectable or metastatic melanoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

and

- ○ The individual has ECOG performance 0-2

and

- ○ The individual has not received funded nivolumab

or

- ○ The individual has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance

and

- ○ The cancer did not progress while the individual was on nivolumab

and

- ○ The individual has been diagnosed in the metastatic or unresectable stage III or IV setting

or

- ○ The individual did not receive treatment in the perioperative setting with a PD-1/PD-L1 inhibitor

or

- ○ The individual received treatment in the perioperative setting with a PD-1/PD-L1 inhibitor

and

- ○ The individual did not experience disease recurrence while on treatment with that PD-1/PD-L1 inhibitor

and

- ○ The individual did not experience disease recurrence within six months of completing perioperative treatment with a PD-1/PD-L1 inhibitor

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

CONTINUATION – unresectable or metastatic melanoma, less than 24 months on treatment
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual's disease has had a complete response to treatment
  or
- ○ The individual's disease has had a partial response to treatment
  or
- ○ The individual has stable disease

and

- ○ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

or

- ○ The individual has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression

and

- ○ The individual has signs of disease progression

and

- ○ Disease has not progressed during previous treatment with pembrolizumab

CONTINUATION – unresectable or metastatic melanoma, more than 24 months on treatment
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The individual has been on treatment for more than 24 months

and

- ○ The individual's disease has had a complete response to treatment
  or
- ○ The individual's disease has had a partial response to treatment
  or
- ○ The individual has stable disease

and

- ○ Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period

and

- ○ The treatment remains clinically appropriate and the individual is benefitting from the treatment

or

- ○ The individual has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression

and

- ○ The individual has signs of disease progression

and

- ○ Disease has not progressed during previous treatment with pembrolizumab

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

INITIATION – non-small cell lung cancer first-line monotherapy
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer

and

- ○ Patient has not had chemotherapy for their disease in the palliative setting

and

- ○ Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC

and

- ○ For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain

and

- ○ Pembrolizumab to be used as monotherapy

and

- ○ There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 50% as determined by a validated test unless not possible to ascertain

or

- ○ There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 1% as determined by a validated test unless not possible to ascertain

and

- ○ Chemotherapy is determined to be not in the best interest of the patient based on clinician assessment

and

- ○ Patient has an ECOG 0-2

and

- ○ Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

CONTINUATION – non-small cell lung cancer first-line monotherapy
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient's disease has had a complete response to treatment

or

- ○ Patient's disease has had a partial response to treatment

or

- ○ Patient has stable disease

and

- ○ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

and

- ○ No evidence of disease progression

and

- ○ The treatment remains clinically appropriate and patient is benefitting from treatment

and

- ○ Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent)

and

- ○ Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

INITIATION – non-small cell lung cancer first-line combination therapy
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer

and

- ○ The patient has not had chemotherapy for their disease in the palliative setting

and

- ○ Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC

and

- ○ For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain

and

- ○ Pembrolizumab to be used in combination with platinum-based chemotherapy

and

- ○ Patient has an ECOG 0-2

and

- ○ Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

CONTINUATION – non-small cell lung cancer first-line combination therapy
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient's disease has had a complete response to treatment

or

- ○ Patient's disease has had a partial response to treatment

or

- ○ Patient has stable disease

and

- ○ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

and

- ○ No evidence of disease progression

and

- ○ The treatment remains clinically appropriate and patient is benefitting from treatment

and

- ○ Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent)

and

- ○ Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

INITIATION – breast cancer, advanced
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment

or

- ○ Patient has recurrent or de novo unresectable, inoperable locally advanced triple-negative breast cancer (that does not express ER, PR or HER2 IHC3+ or ISH+ [including FISH or other technology])

or

- ○ Patient has recurrent or de novo metastatic triple-negative breast cancer (that does not express ER, PR or HER2 IHC3+ or ISH+ [including FISH or other technology]

and

- ○ Patient is treated with palliative intent

and

- ○ Patient's cancer has confirmed PD-L1 Combined Positive Score (CPS) is greater than or equal to 10

and

- ○ Patient has received no prior systemic therapy in the palliative setting

and

- ○ Patient has an ECOG score of 0–2

and

- ○ Pembrolizumab is to be used in combination with chemotherapy

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

and

- ○ Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

CONTINUATION – breast cancer, advanced
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient's disease has had a complete response to treatment

or

- ○ Patient's disease has had a partial response to treatment

or

- ○ Patient has stable disease

and

- ○ No evidence of disease progression

and

- ○ Response to treatment in target lesions has been determined by a comparable radiologic assessment following the most recent treatment period

and

- ○ Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent)

and

- ○ Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

INITIATION – head and neck squamous cell carcinoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment

or

- ○ Patient has recurrent or metastatic head and neck squamous cell carcinoma of mucosal origin (excluding nasopharyngeal carcinoma) that is incurable by local therapies

and

- ○ Patient has not received prior systemic therapy in the recurrent or metastatic setting

and

- ○ Patient has a positive PD-L1 combined positive score (CPS) of greater than or equal to 1

and

- ○ Patient has an ECOG performance score of 0-2

and

- ○ Pembrolizumab to be used in combination with platinum-based chemotherapy

or

- ○ Pembrolizumab to be used as monotherapy

and

- ○ Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

CONTINUATION – head and neck squamous cell carcinoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient's disease has had a complete response to treatment
- **or** ○ Patient's disease has had a partial response to treatment
- **or** ○ Patient has stable disease

and

- ○ No evidence of disease progression

and

- ○ Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent)

and

- ○ Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

INITIATION – MSI-H/dMMR advanced colorectal cancer
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment
- **or**
  - ○ Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer
  - **or** ○ Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer
  - **and** ○ Individual is treated with palliative intent
  - **and** ○ Individual has not previously received funded treatment with pembrolizumab for MSI-H/dMMR advanced colorectal cancer
  - **and** ○ Individual has an ECOG performance score of 0-2
  - **and** ○ Baseline measurement of overall tumour burden is documented clinically and radiologically
  - **and** ○ Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

CONTINUATION – MSI-H/dMMR advanced colorectal cancer
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ No evidence of disease progression

and

- ○ Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent)

and

- ○ Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

INITIATION – Urothelial carcinoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment

or

- ○ Patient has inoperable locally advanced (T4) or metastatic urothelial carcinoma

and

- ○ Patient has an ECOG performance score of 0-2

and

- ○ Patient has documented disease progression following treatment with chemotherapy

and

- ○ Pembrolizumab to be used as monotherapy at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

CONTINUATION – Urothelial carcinoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient's disease has had a complete response to treatment

or

- ○ Patient's disease has had a partial response to treatment

or

- ○ Patient has stable disease

and

- ○ No evidence of disease progression

and

- ○ Pembrolizumab is to be used as monotherapy at a maximum dose of 200 mg every three weeks (or equivalent)

and

- ○ Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pembrolizumab *- continued*

INITIATION – relapsed/refractory Hodgkin lymphoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment

or

- ○ Individual has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy

  and

  ○ Individual is ineligible for autologous stem cell transplant

  or

  ○ Individual has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant

and

- ○ Individual has not previously received funded pembrolizumab for relapsed/refractory Hodgkin lymphoma

and

- ○ Pembrolizumab to be administered at doses no greater than 200 mg once every 3 weeks

CONTINUATION – relapsed/refractory Hodgkin lymphoma
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has received a partial or complete response to pembrolizumab

and

- ○ Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Durvalumab

INITIATION – Non-small cell lung cancer
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has histologically or cytologically documented stage III, locally advanced, unresectable non-small cell lung cancer (NSCLC)

or

- ○ Patient has histologically or cytologically documented stage IIb (T1N2a only), locally advanced, unresectable non-small cell lung cancer (NSCLC)

and

- ○ Patient has received two or more cycles of platinum-based chemotherapy concurrently with definitive radiation therapy

and

- ○ Patient has no disease progression following the second or subsequent cycle of platinum-based chemotherapy with definitive radiation therapy treatment

and

- ○ Patient has a ECOG performance status of 0 or 1

and

- ○ Patient has completed last radiation dose within 8 weeks of starting treatment with durvalumab

and

- ○ Patient must not have received prior PD-1 or PD-L1 inhibitor therapy for this condition

and

- ○ Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks

or

- ○ Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks

and

- ○ Treatment with durvalumab to cease upon signs of disease progression

CONTINUATION – Non-small cell lung cancer
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ The treatment remains clinically appropriate and the patient is benefitting from treatment

and

- ○ Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks

or

- ○ Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks

and

- ○ Treatment with durvalumab to cease upon signs of disease progression

and

- ○ Total continuous treatment duration must not exceed 12 months

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Atezolizumab

INITIATION – non-small cell lung cancer second line monotherapy
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has locally advanced or metastatic non-small cell lung cancer

and

- ○ Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC

and

- ○ For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain

and

- ○ Patient has an ECOG 0-2

and

- ○ Patient has documented disease progression following treatment with at least two cycles of platinum-based chemotherapy

and

- ○ Atezolizumab is to be used as monotherapy at a dose of 1200 mg every three weeks (or equivalent) for a maximum of 16 weeks

and

- ○ Baseline measurement of overall tumour burden is documented clinically and radiologically

CONTINUATION – non-small cell lung cancer second line monotherapy
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient's disease has had a complete response to treatment

or

- ○ Patient's disease has had a partial response to treatment

or

- ○ Patient has stable disease

and

- ○ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

and

- ○ No evidence of disease progression

and

- ○ The treatment remains clinically appropriate and patient is benefitting from treatment

and

- ○ Atezolizumab to be used at a maximum dose of 1200 mg every three weeks (or equivalent)

and

- ○ Treatment with atezolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Atezolizumab *- continued*

INITIATION – unresectable hepatocellular carcinoma
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient is currently on treatment with atezolizumab and met all remaining criteria prior to commencing treatment

or

- ○ Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma

and

- ○ Patient has preserved liver function (Child-Pugh A)

and

- ○ Transarterial chemoembolisation (TACE) is unsuitable

and

- ○ Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma

or

- ○ Patient received funded lenvatinib before 1 March 2025

or

- ○ Patient has experienced treatment-limiting toxicity from treatment with lenvatinib

and

- ○ No disease progression since initiation of lenvatinib

and

- ○ Patient has an ECOG performance status of 0-2

and

- ○ To be given in combination with bevacizumab

CONTINUATION – unresectable hepatocellular carcinoma
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ No evidence of disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ipilimumab

INITIATION – renal cell carcinoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ The patient is currently on treatment with ipilimumab and met all remaining criteria prior to commencing treatment

or

- ○ The patient has metastatic renal cell carcinoma

and

- ○ The patient is treatment naive

and

- ○ The patient has ECOG performance status 0-2

and

- ○ The disease is predominantly of clear cell histology

and

- ○ The patient has sarcomatoid histology

or

- ○ Haemoglobin levels less than the lower limit of normal

or

- ○ Corrected serum calcium level greater than 10 mg/dL (2.5 mmol/L)

or

- ○ Neutrophils greater than the upper limit of normal

or

- ○ Platelets greater than the upper limit of normal

or

- ○ Interval of less than 1 year from original diagnosis to the start of systemic therapy

or

- ○ Karnofsky performance score of less than or equal to 70

and

- ○ Ipilimumab is to be used at a maximum dose of 1 mg/kg for up to four cycles in combination with nivolumab

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Everolimus

INITIATION
Re-assessment required after 3 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a neurologist or oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has tuberous sclerosis

and

- ○ Patient has progressively enlarging sub-ependymal giant cell astrocytomas (SEGAs) that require treatment

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a neurologist or oncologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Documented evidence of SEGA reduction or stabilisation by MRI within the last 3 months

and

- ○ The treatment remains appropriate and the patient is benefiting from treatment

and

- ○ Everolimus to be discontinued at progression of SEGAs

INITIATION – renal cell carcinoma
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ The patient has metastatic renal cell carcinoma

and

- ○ The disease is of predominant clear-cell histology

and

- ○ The patient has documented disease progression following one previous line of treatment

and

- ○ The patient has an ECOG performance status of 0-2

and

- ○ Everolimus is to be used in combination with lenvatinib

or

- ○ Patient has received funded treatment with nivolumab for the second line treatment of metastatic renal cell carcinoma

and

- ○ Patient has experienced treatment limiting toxicity from treatment with nivolumab

and

- ○ Everolimus is to be used in combination with lenvatinib

and

- ○ There is no evidence of disease progression

CONTINUATION – renal cell carcinoma
Re-assessment required after 4 months
Prerequisites (tick box where appropriate)

- ○ There is no evidence of disease progression

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sirolimus

INITIATION

Prerequisites (tick box where appropriate)

○ For rescue therapy for an organ transplant recipient

Note: Rescue therapy defined as unresponsive to calcineurin inhibitor treatment as defined by refractory rejection; or intolerant to calcineurin inhibitor treatment due to any of the following:

- GFR < 30 ml/min; or
- Rapidly progressive transplant vasculopathy; or
- Rapidly progressive obstructive bronchiolitis; or
- HUS or TTP; or
- Leukoencepthalopathy; or
- Significant malignant disease

INITIATION – severe non-malignant lymphovascular malformations*

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

○ Patient has severe non-malignant lymphovascular malformation*

and

○ Malformations are not adequately controlled by sclerotherapy and surgery

or

○ Malformations are widespread/extensive and sclerotherapy and surgery are not considered clinically appropriate

or

○ Sirolimus is to be used to reduce malformation prior to consideration of surgery

and

○ Patient is being treated by a specialist lymphovascular malformation multi-disciplinary team

and

○ Patient has measurable disease as defined by RECIST version 1.1 (see Note)

CONTINUATION – severe non-malignant lymphovascular malformations*

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

○ Patient's disease has had either a complete response or a partial response to treatment, or patient has stable disease according to RECIST version 1.1 (see Note)

or

○ Patient's disease has stabilised or responded clinically and disease response to treatment has been clearly documents in patient notes

and

○ No evidence of progressive disease

and

○ The treatment remains clinically appropriate and the patient is benefitting from the treatment

Note: Baseline assessment and disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer et al. Eur J Cancer 2009;45:228-47)

Indications marked with * are unapproved indications

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sirolimus *- continued*

INITIATION – renal angiomyolipoma(s) associated with tuberous sclerosis complex*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a nephrologist or urologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has tuberous sclerosis complex*

and

- ○ Evidence of renal angiomyolipoma(s) measuring 3 cm or greater and that have shown interval growth

CONTINUATION – renal angiomyolipoma(s) associated with tuberous sclerosis complex*
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Documented evidence of renal angiomyolipoma reduction or stability by magnetic resonance imaging (MRI) or ultrasound

and

- ○ Demonstrated stabilisation or improvement in renal function

and

- ○ The patient has not experienced angiomyolipoma haemorrhage or significant adverse effects to sirolimus treatment

and

- ○ The treatment remains appropriate and the patient is benefitting from treatment

Note: Indications marked with * are unapproved indications

INITIATION – refractory seizures associated with tuberous sclerosis complex*
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has epilepsy with a background of documented tuberous sclerosis complex*

and

- ○ Vigabatrin has been trialled and has not adequately controlled seizures

and

- ○ Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least two of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note)

or

- ○ Vigabatrin is contraindicated

and

- ○ Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least three of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note)

and

- ○ Seizures have a significant impact on quality of life

and

- ○ Patient has been assessed and surgery is considered inappropriate for this patient, or the patient has been assessed and would benefit from mTOR inhibitor treatment prior to surgery

Note: Those of childbearing potential are not required to trial phenytoin sodium, sodium valproate, and topiramate. Those who can father children are not required to trial sodium valproate.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Sirolimus *- continued*

CONTINUATION – refractory seizures associated with tuberous sclerosis complex*
Re-assessment required after 12 months

Prerequisites (tick box where appropriate)

❍ Prescribed by, or recommended by a neurologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ Demonstrated significant and sustained improvement in seizure rate (e.g. 50% reduction in seizure frequency) or severity and/or patient quality of life compared with baseline prior to starting sirolimus treatment

Note: Indications marked with * are unapproved indications

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Bacillus calmette-guerin (BCG)

INITIATION

Prerequisites (tick box where appropriate)

- ○ For use in bladder cancer

I confirm that the above details are correct:

Signed: ..... Date: .....

RS2120 - Upadacitinib

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Upadacitinib

INITIATION – Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ The individual has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis

and

- ○ The individual has experienced intolerable side effects with adalimumab and/or etanercept

or

- ○ The individual has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis

and

- ○ Rituximab is not clinically appropriate

or

- ○ The individual is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor

or

- ○ The individual has been started on rituximab for rheumatoid arthritis in a Health NZ Hospital

and

- ○ The individual has experienced intolerable side effects with rituximab

or

- ○ At four months following the initial course of rituximab the individual has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis

CONTINUATION – Rheumatoid Arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Following 6 months' initial treatment, the individual has experienced at least a 50% decrease in active joint count from baseline

or

- ○ On subsequent reapplications, the individual has experienced at least a continuing 30% improvement in active joint count from baseline

INITIATION – Atopic dermatitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Individual is currently on treatment with upadacitinib for atopic dermatitis and met all remaining criteria prior to commencing treatment

or

- ○ Individual has moderate to severe atopic dermatitis, severity as defined by an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 or a Dermatology Life Quality Index (DLQI) score of greater than or equal to 10

and

- ○ Individual has received insufficient benefit from topical therapy (including topical corticosteroids or topical calcineurin inhibitors) for a 28-day trial within the last 6 months, unless contraindicated to all

and

- ○ Individual has trialled and received insufficient benefit from at least one systemic therapy for a minimum of three months (eg ciclosporin, azathioprine, methotrexate or mycophenolate mofetil), unless contraindicated to all

and

- ○ An EASI assessment or DLQI assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course

and

- ○ The most recent EASI or DQLI assessment is no more than 1 month old at the time of application

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Upadacitinib *- continued*

CONTINUATION – Atopic dermatitis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Individual has received a 75% or greater reduction in EASI score (EASI 75) as compared to baseline EASI prior to commencing upadacitinib

or

- ○ Individual has received a DLQI improvement of 4 or more as compared to baseline DLQI prior to commencing upadacitinib

INITIATION – Crohn's disease – adult
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Individual is currently on treatment with upadacitinib for Crohn's disease and met all remaining criteria prior to commencing treatment

or

- ○ Individual has active Crohn's disease

and

- ○ Individual has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

- ○ Individual meets the initiation criteria for prior biologic therapies for Crohn's disease

and

- ○ Other biologic therapies for Crohn's disease are contraindicated

CONTINUATION – Crohn's disease – adult
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ CDAI score has reduced by 100 points from the CDAI score when the individual was initiated on biologic therapy

or

- ○ HBI score has reduced by 3 points from when individual was initiated on biologic therapy

or

- ○ CDAI score is 150 or less

or

- ○ HBI score is 4 or less

or

- ○ The individual has experienced an adequate response to treatment, but CDAI score cannot be assessed

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Upadacitinib *- continued*

INITIATION – Crohn's disease – children
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Individual is currently on treatment with upadacitinib for Crohn's disease and met all remaining criteria prior to commencing treatment

or

- ○ Child has active Crohn's disease

and

- ○ Child has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

- ○ Child meets the initiation criteria for prior biologic therapies for Crohn's disease

and

- ○ Other biologic therapies for Crohn's disease are contraindicated

CONTINUATION – Crohn's disease – children
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ PCDAI score has reduced by 10 points from when the child was initiated on treatment

or

- ○ PCDAI score is 15 or less

or

- ○ The child has experienced an adequate response to treatment, but PCDAI score cannot be assessed

Note: Indications marked with * are unapproved indications.

INITIATION – Ulcerative colitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Individual is currently on treatment with upadacitinib for ulcerative colitis and met all remaining criteria prior to commencing treatment

or

- ○ Individual has active ulcerative colitis

and

- ○ Individual has had an initial approval for prior biologic therapy for ulcerative colitis and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

- ○ Individual meets the initiation criteria for prior biologic therapies for ulcerative colitis

and

- ○ Other biologic therapies for ulcerative colitis are contraindicated

CONTINUATION – Ulcerative colitis
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ The SCCAI score has reduced by 2 points or more from the SCCAI score when the individual was initiated on treatment

or

- ○ PUCAI score has reduced by 10 points or more from the PUCAI score when the individual was initiated on treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Respiratory System and Allergies

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Icatibant

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a clinical immunologist or relevant specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Supply for anticipated emergency treatment of laryngeal/oro-pharyngeal or severe abdominal attacks of acute hereditary angioedema (HAE) for patients with confirmed diagnosis of C1-esterase inhibitor deficiency

and

- ○ The patient has undergone product training and has agreed upon an action plan for self-administration

CONTINUATION
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ The treatment remains appropriate and the patient is benefiting from treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adrenaline

INITIATION – anaphylaxis

Prerequisites (tick boxes where appropriate)

- ○ Patient has experienced a previous anaphylactic reaction which has resulted in presentation to a hospital or emergency department

or

- ○ Patient has been assessed to be at significant risk of anaphylaxis by a relevant practitioner

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Bee venom

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ RAST or skin test positive

and

- ○ Patient has had severe generalised reaction to the sensitising agent

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Paper wasp venom

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ RAST or skin test positive

and

- ○ Patient has had severe generalised reaction to the sensitising agent

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Yellow jacket wasp venom

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ RAST or skin test positive

and

- ○ Patient has had severe generalised reaction to the sensitising agent

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Long-acting muscarinic antagonists with long-acting beta-adrenoceptor agonists

INITIATION
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Patient has been stabilised on a long acting muscarinic antagonist

and

- ○ The prescriber considers that the patient would receive additional benefit from switching to a combination product

CONTINUATION
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Patient is compliant with the medication

and

- ○ Patient has experienced improved COPD symptom control (prescriber determined)

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Fluticasone furoate with umeclidinium and vilanterol

INITIATION

Prerequisites (tick boxes where appropriate)

❍ Patient has a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible

and

❍ Patient is currently receiving an inhaled corticosteroid with long acting beta-2 agonist (ICS/LABA) or a long acting muscarinic antagonist with long acting beta-2 agonist (LAMA/LABA)

and

Clinical criteria:

❍ Patient has a COPD Assessment Test (CAT) score greater than 10

or

❍ Patient has had 2 or more exacerbations in the previous 12 months

or

❍ Patient has had one exacerbation requiring hospitalisation in the previous 12 months

or

❍ Patient has had an eosinophil count greater than or equal to 0.3 × 10^9 cells/L in the previous 12 months

or

❍ Patient is currently receiving multiple inhaler triple therapy (inhaled corticosteroid with long acting muscarinic antagonist and long acting beta-2 agonist – ICS/LAMA/LABA) and met at least one of the clinical criteria above prior to commencing multiple inhaler triple therapy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Budesonide with glycopyrronium and eformoterol

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient has a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible

and

- ○ Patient is currently receiving an inhaled corticosteroid with long acting beta-2 agonist (ICS/LABA) or a long acting muscarinic antagonist with long acting beta-2 agonist (LAMA/LABA)

and

Clinical criteria:

- ○ Patient has a COPD Assessment Test (CAT) score greater than 10

or

- ○ Patient has had 2 or more exacerbations in the previous 12 months

or

- ○ Patient has had one exacerbation requiring hospitalisation in the previous 12 months

or

- ○ Patient has had an eosinophil count greater than or equal to 0.3 × 10^9 cells/L in the previous 12 months

or

- ○ Patient is currently receiving multiple inhaler triple therapy (inhaled corticosteroid with long-acting muscarinic antagonist and long-acting beta-2 agonist – ICS/LAMA/LABA) and met at least one of the clinical criteria above prior to commencing multiple inhaler therapy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pirfenidone

INITIATION – idiopathic pulmonary fibrosis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist

and

- ○ Forced vital capacity is between 50% and 90% predicted

and

- ○ Pirfenidone is to be discontinued at disease progression (See Notes)

and

- ○ Pirfenidone is not to be used in combination with subsidised nintedanib

and

- ○ The patient has not previously received treatment with nintedanib

or

- ○ Patient has previously received nintedanib, but discontinued nintedanib within 12 weeks due to intolerance

or

- ○ Patient has previously received nintedanib, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with nintedanib)

CONTINUATION – idiopathic pulmonary fibrosis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment

and

- ○ Pirfenidone is not to be used in combination with subsidised nintedanib

and

- ○ Pirfenidone is to be discontinued at disease progression (See Note)

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Nintedanib

INITIATION – idiopathic pulmonary fibrosis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist

and

- ○ Forced vital capacity is between 50% and 90% predicted

and

- ○ Nintedanib is to be discontinued at disease progression (See Note)

and

- ○ Nintedanib is not to be used in combination with subsidised pirfenidone

and

- ○ The patient has not previously received treatment with pirfenidone

or

- ○ Patient has previously received pirfenidone, but discontinued pirfenidone within 12 weeks due to intolerance

or

- ○ Patient has previously received pirfenidone, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with pirfenidone)

CONTINUATION – idiopathic pulmonary fibrosis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment

and

- ○ Nintedanib is not to be used in combination with subsidised pirfenidone

and

- ○ Nintedanib is to be discontinued at disease progression (See Note)

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Ivacaftor

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory specialist or paediatrician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has been diagnosed with cystic fibrosis

and

- ○ Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele

or

- ○ Patient must have other gating (class III) mutation (G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N and S549R) in the CFTR gene on at least 1 allele

and

- ○ Patients must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system

and

- ○ Treatment with ivacaftor must be given concomitantly with standard therapy for this condition

and

- ○ Patient must not have an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing treatment with ivacaftor

and

- ○ The dose of ivacaftor will not exceed one tablet or one sachet twice daily

and

- ○ Applicant has experience and expertise in the management of cystic fibrosis

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Elexacaftor with tezacaftor, ivacaftor and ivacaftor

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient has been diagnosed with cystic fibrosis

and

- ○ Patient is 6 years of age or older

and

- ○ Patient has two cystic fibrosis-causing mutations in the cystic fibrosis transmembrane regulator (CFTR) gene (one from each parental allele)

or

- ○ Patient has a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system

and

- ○ Patient has a heterozygous or homozygous F508del mutation

or

- ○ Patient has a G551D mutation or other mutation responsive in vitro to elexacaftor/tezacaftor/ivacaftor (see note a)

and

- ○ The treatment must be the sole funded CFTR modulator therapy for this condition

and

- ○ Treatment with elexacaftor/tezacaftor/ivacaftor must be given concomitantly with standard therapy for this condition

Note:

a) Eligible mutations are listed in the Food and Drug Administration (FDA) Trikafta prescribing information https://nctr-crs.fda.gov/fdalabel/services/spl/set-ids/f354423a-85c2-41c3-a9db-0f3aee135d8d/spl-doc

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Dornase alfa

INITIATION – cystic fibrosis
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a respiratory physician or paediatrician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has a confirmed diagnosis of cystic fibrosis

and

- ○ Patient has previously undergone a trial with, or is currently being treated with, hypertonic saline

and

- ○ Patient has required one or more hospital inpatient respiratory admissions in the previous 12 month period

or

- ○ Patient has had 3 exacerbations due to CF, requiring oral or intravenous (IV) antibiotics in in the previous 12 month period

or

- ○ Patient has had 1 exacerbation due to CF, requiring oral or IV antibiotics in the previous 12 month period and a Brasfield score of < 22/25

or

- ○ Patient has a diagnosis of allergic bronchopulmonary aspergillosis (ABPA)

CONTINUATION – cystic fibrosis
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a respiratory physician or paediatrician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The treatment remains appropriate and the patient continues to benefit from treatment

INITIATION – significant mucus production
Re-assessment required after 4 weeks
Prerequisites (tick boxes where appropriate)

- ○ Patient is an in-patient

and

- ○ The mucus production cannot be cleared by first line chest techniques

INITIATION – pleural emphyema
Re-assessment required after 3 days
Prerequisites (tick boxes where appropriate)

- ○ Patient is an in-patient

and

- ○ Patient diagnoses with pleural emphyema

I confirm that the above details are correct:

Signed: ..... Date: .....

Sensory Organs

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Dexamethasone

INITIATION – Diabetic macular oedema
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an ophthalmologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patients have diabetic macular oedema with pseudophakic lens

and

- ○ Patient has reduced visual acuity of between 6/9 – 6/48 with functional awareness of reduction in vision

and

- ○ Patient's disease has progressed despite 3 injections with bevacizumab

or

- ○ Patient is unsuitable or contraindicated to treatment with anti-VEGF agents

and

- ○ Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year

CONTINUATION – Diabetic macular oedema
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an ophthalmologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient's vision is stable or has improved (prescriber determined)

and

- ○ Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year

INITIATION – Women of child bearing age with diabetic macular oedema
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by an ophthalmologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patients have diabetic macular oedema

and

- ○ Patient has reduced visual acuity of between 6/9 – 6/48 with functional awareness of reduction in vision

and

- ○ Patient is of child bearing potential and has not yet completed a family

and

- ○ Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Dexamethasone *- continued*

CONTINUATION – Women of child bearing age with diabetic macular oedema
Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by an ophthalmologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ Patient's vision is stable or has improved (prescriber determined)

and

❍ Patient is of child bearing potential and has not yet completed a family

and

❍ Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year

I confirm that the above details are correct:

Signed: ..... Date: .....

Various

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Deferasirox

INITIATION
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia

and

- ○ Deferasirox is to be given at a daily dose not exceeding 40 mg/kg/day

and

- ○ Treatment with maximum tolerated doses of deferiprone monotherapy or deferiprone and desferrioxamine combination therapy have proven ineffective as measured by serum ferritin levels, liver or cardiac MRI T2*

or

- ○ Treatment with deferiprone has resulted in severe persistent vomiting or diarrhoea

or

- ○ Treatment with deferiprone has resulted in arthritis

or

- ○ Treatment with deferiprone is contraindicated due to a history of agranulocytosis (defined as an absolute neutrophil count (ANC) of < 0.5 cells per µL) or recurrent episodes (greater than 2 episodes) of moderate neutropenia (ANC 0.5 - 1.0 cells per µL)

CONTINUATION
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ For the first renewal following 2 years of therapy, the treatment has been tolerated and has resulted in clinical improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels

or

- ○ For subsequent renewals, the treatment has been tolerated and has resulted in clinical stability or continued improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Deferiprone

INITIATION

Prerequisites (tick box where appropriate)

- ○ Patient has been diagnosed with chronic iron overload due to congenital inherited anaemia or acquired red cell aplasia

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Povidone-iodine - Vaginal tab 200 mg

INITIATION

Prerequisites (tick box where appropriate)

- ○ Rectal administration pre-prostate biopsy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Chlorhexidine with cetrimide

INITIATION
Re-assessment required after 3 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has burns that are greater than 30% of total body surface area (BSA)

and

- ○ For use in the perioperative preparation and cleansing of large burn areas requiring debridement/skin grafting

and

- ○ The use of 30 ml ampoules is impractical due to the size of the area to be covered

CONTINUATION
Re-assessment required after 3 months
Prerequisites (tick box where appropriate)

- ○ The treatment remains appropriate for the patient and the patient is benefiting from the treatment

I confirm that the above details are correct:

Signed: ..... Date: .....

Special Foods

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Carbohydrate

INITIATION – Use as an additive

Prerequisites (tick boxes where appropriate)

- ○ Cystic fibrosis

or

- ○ Chronic kidney disease

or

- ○ Cancer in children

or

- ○ Cancers affecting alimentary tract where there are malabsorption problems in patients over the age of 20 years

or

- ○ Faltering growth in an infant/child

or

- ○ Bronchopulmonary dysplasia

or

- ○ Premature and post premature infant

or

- ○ Inborn errors of metabolism

INITIATION – Use as a module

Prerequisites (tick box where appropriate)

- ○ For use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Fat

INITIATION – Use as an additive

Prerequisites (tick boxes where appropriate)

- ○ Patient has inborn errors of metabolism

or

- ○ Faltering growth in an infant/child

or

- ○ Bronchopulmonary dysplasia

or

- ○ Fat malabsorption

or

- ○ Lymphangiectasia

or

- ○ Short bowel syndrome

or

- ○ Infants with necrotising enterocolitis

or

- ○ Biliary atresia

or

- ○ For use in a ketogenic diet

or

- ○ Chyle leak

or

- ○ Ascites

or

- ○ Patient has increased energy requirements, and for whom dietary measures have not been successful

INITIATION – Use as a module

Prerequisites (tick box where appropriate)

- ○ For use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Protein

INITIATION – Use as an additive

Prerequisites (tick boxes where appropriate)

- ○ Protein losing enteropathy

or

- ○ High protein needs

INITIATION – Use as a module

Prerequisites (tick box where appropriate)

- ○ For use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Carbohydrate and fat supplement

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Infant or child aged four years or under

and

- ○ Cystic fibrosis

or

- ○ Cancer in children

or

- ○ Faltering growth

or

- ○ Bronchopulmonary dysplasia

or

- ○ Premature and post premature infants

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Metabolic Products

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For the dietary management of inherited metabolic disease

or

- ○ Patient has adrenoleukodystrophy

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Diabetic Products

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For patients with type I or type II diabetes suffering weight loss and malnutrition that requires nutritional support

or

- ○ For patients with pancreatic insufficiency

or

- ○ For patients who have, or are expected to, eat little or nothing for 5 days

or

- ○ For patients who have a poor absorptive capacity and/or high nutrient losses and/or increased nutritional needs from causes such as catabolism

or

- ○ For use pre- and post-surgery

or

- ○ For patients being tube-fed

or

- ○ For tube-feeding as a transition from intravenous nutrition

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Elemental and Semi-Elemental Products

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Malabsorption

or

- ○ Short bowel syndrome

or

- ○ Enterocutaneous fistulas

or

- ○ Eosinophilic enteritis (including oesophagitis)

or

- ○ Inflammatory bowel disease

or

- ○ Acute pancreatitis where standard feeds are not tolerated

or

- ○ Patients with multiple food allergies requiring enteral feeding

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Fat-modified feed

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient has metabolic disorders of fat metabolism

or

- ○ Patient has a chyle leak

or

- ○ Modified as a modular feed, made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule, for adults

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Hepatic Products

INITIATION

Prerequisites (tick box where appropriate)

○ For children (up to 18 years) who require a liver transplant

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

High Calorie Products

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient is fluid volume or rate restricted

or

- ○ Patient requires low electrolyte

or

- ○ Cystic fibrosis

or

- ○ Any condition causing malabsorption

or

- ○ Faltering growth in an infant/child

or

- ○ Increased nutritional requirements

and

- ○ Patient has substantially increased metabolic requirements

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

High protein enteral feed

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ The patient has a high protein requirement

and

- ○ Patient has liver disease

or

- ○ Patient is obese (BMI > 30) and is undergoing surgery

or

- ○ Patient is fluid restricted

or

- ○ Patient's needs cannot be more appropriately met using high calorie product

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Extensively hydrolysed formula

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Cows' milk formula is inappropriate due to severe intolerance or allergy to its protein content

and

- ○ Soy milk formula has been reasonably trialled without resolution of symptoms

or

- ○ Soy milk formula is considered clinically inappropriate or contraindicated

or

- ○ Severe malabsorption

or

- ○ Short bowel syndrome

or

- ○ Intractable diarrhoea

or

- ○ Biliary atresia

or

- ○ Cholestatic liver diseases causing malsorption

or

- ○ Cystic fibrosis

or

- ○ Proven fat malabsorption

or

- ○ Severe intestinal motility disorders causing significant malabsorption

or

- ○ Intestinal failure

or

- ○ For step down from Amino Acid Formula

Note: A reasonable trial is defined as a 2-4 week trial, or signs of an immediate IgE mediated allergic reaction.

CONTINUATION

Prerequisites (tick boxes where appropriate)

- ○ An assessment as to whether the infant can be transitioned to a cows' milk protein or soy infant formula has been undertaken

and

- ○ The outcome of the assessment is that the infant continues to require an extensively hydrolysed infant formula

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Preterm formula

INITIATION

Prerequisites (tick box where appropriate)

- ○ For infants born before 33 weeks' gestation or weighing less than 1.5 kg at birth

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Paediatric oral/enteral feed 1 kcal/ml

INITIATION – Fluid restricted or volume intolerance with faltering growth

Prerequisites (tick boxes where appropriate)

- ○ The patient is fluid restricted or volume intolerant

or

- ○ The patient has increased nutritional requirements due to faltering growth

and

- ○ Patient is under 18 months old and weighs less than 8kg

Note: 'Volume intolerant' patients are those who are unable to tolerate an adequate volume of infant formula to achieve expected growth rate. These patients should have first trialled appropriate clinical alternative treatments, such as concentrating, fortifying and adjusting the frequency of feeding.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Enteral liquid peptide formula

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Patient has impaired gastrointestinal function and either cannot tolerate polymeric feeds, or polymeric feeds are unsuitable

and

- ○ Severe malabsorption

or

- ○ Short bowel syndrome

or

- ○ Intractable diarrhoea

or

- ○ Biliary atresia

or

- ○ Cholestatic liver diseases causing malabsorption

or

- ○ Cystic fibrosis

or

- ○ Proven fat malabsorption

or

- ○ Severe intestinal motility disorders causing significant malabsorption

or

- ○ Intestinal failure

or

  - ○ The patient is currently receiving funded amino acid formula

  and

  - ○ The patient is to be trialled on, or transitioned to, an enteral liquid peptide formula

and

- ○ A semi-elemental or partially hydrolysed powdered feed has been reasonably trialled and considered unsuitable

or

- ○ For step down from intravenous nutrition

Note: A reasonable trial is defined as a 2-4 week trial.

CONTINUATION

Prerequisites (tick boxes where appropriate)

- ○ An assessment as to whether the patient can be transitioned to a cows milk protein or soy infant formula or extensively hydrolysed formula has been undertaken

and

- ○ The outcome of the assessment is that the patient continues to require an enteral liquid peptide formula

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Amino acid formula

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption

or

- ○ History of anaphylaxis to cows' milk protein formula or dairy products

or

- ○ Eosinophilic oesophagitis

or

- ○ Ultra-short gut

or

- ○ Severe Immune deficiency

CONTINUATION

Prerequisites (tick boxes where appropriate)

- ○ An assessment as to whether the infant can be transitioned to a cows' milk protein, soy, or extensively hydrolysed infant formula has been undertaken

and

- ○ The outcome of the assessment is that the infant continues to require an amino acid infant formula

and

- ○ Amino acid formula is required for a nutritional deficit

INITIATION – patients who are currently funded under RS1502 or SA1557

Re-assessment required after 3 months

Prerequisites (tick boxes where appropriate)

- ○ Patient has a valid initiation or renewal approval for extensively hydrolysed formula (RS1502)

and

- ○ Patient is unable to source funded Aptamil powder at this time

and

- ○ The approval only applies to funded dispensings of Neocate Gold and Neocate Syneo

Note: This criteria is short term funding to cover an out-of-stock situation on some extensively hydrolysed formula powder funded under Hospital Restriction RS1502. There is no continuation criteria under this criterion.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

High fat formula

INITIATION

Prerequisites (tick box where appropriate)

- ○ For patients with intractable epilepsy, pyruvate dehydrogenase deficiency or glucose transported type-1 deficiency and other conditions requiring a ketogenic diet

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Paediatric Products

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Child is aged one to ten years

and

- ○ The child is being fed via a tube or a tube is to be inserted for the purposes of feeding

or

- ○ Any condition causing malabsorption

or

- ○ Faltering growth in an infant/child

or

- ○ Increased nutritional requirements

or

- ○ The child is being transitioned from TPN or tube feeding to oral feeding

or

- ○ The child has eaten, or is expected to eat, little or nothing for 3 days

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Low electrolyte oral feed

INITIATION

Prerequisites (tick box where appropriate)

- ○ For children (up to 18 years) with acute or chronic kidney disease

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Low electrolyte oral feed

INITIATION

Prerequisites (tick box where appropriate)

○ For patients with acute or chronic kidney disease

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Preoperative carbohydrate feed 0.5 kcal/ml

INITIATION

Prerequisites (tick box where appropriate)

- ○ Maximum of 400 ml as part of an Enhanced Recovery After Surgery (ERAS) protocol 2 to 3 hours before major abdominal surgery

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

High arginine oral feed 1.4 kcal/ml

INITIATION

Prerequisites (tick box where appropriate)

- ○ Three packs per day for 5 to 7 days prior to major gastrointestinal, head or neck surgery

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Standard Feeds

INITIATION

Prerequisites (tick boxes where appropriate)

For patients with malnutrition, defined as any of the following:

- ○ BMI < 18.5

or

- ○ Greater than 10% weight loss in the last 3-6 months

or

- ○ BMI < 20 with greater than 5% weight loss in the last 3-6 months

or

- ○ For patients who have, or are expected to, eat little or nothing for 5 days

or

- ○ For patients who have a poor absorptive capacity and/or high nutrient losses and/or increased nutritional needs from causes such as catabolism

or

- ○ For use pre- and post-surgery

or

- ○ For patients being tube-fed

or

- ○ For tube-feeding as a transition from intravenous nutrition

or

- ○ For any other condition that meets the community Special Authority criteria

I confirm that the above details are correct:

Signed: ..... Date: .....

Vaccines

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Diphtheria, tetanus, pertussis and polio vaccine

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ A single dose for children up to the age of 7 who have completed primary immunisation

or

- ○ A course of up to four vaccines is funded for catch up programmes for children (to the age of 10 years) to complete full primary immunisation

or

- ○ An additional four doses (as appropriate) are funded for (re-)immunisation for patients post HSCT, or chemotherapy; pre- or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens

or

- ○ Five doses will be funded for children requiring solid organ transplantation

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type B vaccine

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Up to four doses for children under the age of 10 years for primary immunisation

or

- ○ An additional four doses (as appropriate) for (re-)immunisation of children under the age of 18 years post haematopoietic stem cell transplantation

or

- ○ An additional four doses (as appropriate) for (re-)immunisation of children under the age of 10 years who are post chemotherapy; pre or post splenectomy; undergoing renal dialysis and other severely immunosuppressive regimens

or

- ○ Up to five doses for children under the age of 10 years receiving solid organ transplantation

Note: A course of up-to four vaccines is funded for catch up programmes for children (up to and under the age of 10 years) to complete full primary immunisation. Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Bacillus calmette-guerin vaccine

INITIATION

Prerequisites (tick boxes where appropriate)

For infants at increased risk of tuberculosis defined as:

○ Living in a house or family with a person with current or past history of TB

and

○ Having one or more household members or carers who within the last 5 years lived in a country with a rate of TB > or equal to 40 per 100,000 for 6 months or longer

and

○ During their first 5 years will be living 3 months or longer in a country with a rate of TB > or equal to 40 per 100,000

Note: A list of countries with high rates of TB are available at http://www.health.govt.nz/tuberculosis (Search for Downloads) or www.bcgatlas.org/index.php

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Diphtheria, tetanus and pertussis vaccine

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ A single dose for pregnant women in the second or third trimester of each pregnancy; or

or

- ○ A single dose for parents or primary caregivers of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than 3 days, who had not been exposed to maternal vaccination at least 14 days prior to birth; or

or

- ○ A course of up to four doses is funded for children from age 7 up the age of 18 years inclusive to complete full primary immunisation

or

- ○ An additional four doses (as appropriate) are funded for (re-)immunisation for patients post haematopoietic stem cell transplantation or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens

or

- ○ A single dose for vaccination of patients aged from 65 years old

or

- ○ A single dose for vaccination of patients aged from 45 years old who have not had 4 previous tetanus doses

or

- ○ For vaccination of previously unimmunised or partially immunised patients

or

- ○ For revaccination following immunosuppression

or

- ○ For boosting of patients with tetanus-prone wounds

Note: Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Haemophilus influenzae type B vaccine

INITIATION
Re-assessment required after 1 dose
Prerequisites (tick boxes where appropriate)

- ○ For primary vaccination in children

or

- ○ An additional dose (as appropriate) is funded for (re-)immunisation for patients post haematopoietic stem cell transplantation, or chemotherapy; functional asplenic; pre or post splenectomy; pre- or post solid organ transplant, pre- or post cochlear implants, renal dialysis and other severely immunosuppressive regimens

or

- ○ For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician

I confirm that the above details are correct:

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Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Meningococcal (A, C, Y and W-135) conjugate vaccine

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients with HIV, complement deficiency (acquired or inherited), functional or anatomic asplenia or pre or post solid organ transplant

or

- ○ One dose for close contacts of meningococcal cases of any group

or

- ○ One dose for person who has previously had meningococcal disease of any group

or

- ○ A maximum of two doses for bone marrow transplant patients

or

- ○ A maximum of two doses for person pre and post-immunosuppression*

or

- ○ Person is aged between 13 and 25 years, inclusive

and

  - ○ One dose for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons

  or

  - ○ One dose for individuals who turn 13 years of age while living in boarding school hostels

Note: children under seven years of age require two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly.
*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Meningococcal (A, C, Y and W-135) conjugate vaccine

INITIATION – Children under 12 months of age

Prerequisites (tick boxes where appropriate)

- ❍ A maximum of three doses (dependant on age at first dose) for patients pre- and post- splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post- solid organ transplant

or

- ❍ A maximum of three doses (dependant on age at first dose) for close contacts of meningococcal cases of any group

or

- ❍ A maximum of three doses (dependant on age at first dose) for child who has previously had meningococcal disease of any group

or

- ❍ A maximum of three doses (dependant on age at first dose) for bone marrow transplant patients

or

- ❍ A maximum of three doses (dependant on age at first dose) for child pre- and post-immunosuppression*

Note: infants from 6 weeks to less than 6 months of age require a 2+1 schedule, infants from 6 months to less than 12 months of age require a 1+1 schedule. Refer to the Immunisation Handbook for recommended booster schedules with meningococcal ACWY vaccine.
*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pneumococcal (PCV13) conjugate vaccine

INITIATION – Primary course for previously unvaccinated children aged under 5 years
Re-assessment required after 3 doses
Prerequisites (tick box where appropriate)

- ○ A primary course of three doses for previously unvaccinated children up to the age of 59 months inclusive

INITIATION – High risk individuals who have received PCV10
Re-assessment required after 2 doses
Prerequisites (tick box where appropriate)

- ○ Two doses are funded for high risk individuals (over the age of 12 months and under 18 years) who have previously received two doses of the primary course of PCV10

INITIATION – High risk children aged under 5 years
Re-assessment required after 4 doses
Prerequisites (tick boxes where appropriate)

- ○ Up to an additional four doses (as appropriate) are funded for the (re)immunisation of high-risk children aged under 5 years

and

- ○ On immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response

or

- ○ Primary immune deficiencies

or

- ○ HIV infection

or

- ○ Renal failure, or nephrotic syndrome

or

- ○ Are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant)

or

- ○ Cochlear implants or intracranial shunts

or

- ○ Cerebrospinal fluid leaks

or

- ○ Receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater

or

- ○ Chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy)

or

- ○ Pre term infants, born before 28 weeks gestation

or

- ○ Cardiac disease, with cyanosis or failure

or

- ○ Diabetes

or

- ○ Down syndrome

or

- ○ Who are pre-or post-splenectomy, or with functional asplenia

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pneumococcal (PCV13) conjugate vaccine *- continued*

INITIATION – High risk individuals 5 years and over
Re-assessment required after 4 doses
Prerequisites (tick box where appropriate)

❍ Up to an additional four doses (as appropriate) are funded for the (re-)immunisation of individuals 5 years and over with HIV, pre or post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post- solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, intracranial shunts, cerebrospinal fluid leaks or primary immunodeficiency

INITIATION – Testing for primary immunodeficiency diseases
Prerequisites (tick box where appropriate)

❍ For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician

Note: Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Pneumococcal (PPV23) polysaccharide vaccine

INITIATION – High risk patients
Re-assessment required after 3 doses
Prerequisites (tick box where appropriate)

- ○ For patients with HIV, for patients post haematopoietic stem cell transplant, or chemotherapy; pre- or post-splenectomy; or with functional asplenia, pre- or post-solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency

INITIATION – High risk children
Re-assessment required after 2 doses
Prerequisites (tick boxes where appropriate)

- ○ Patient is a child under 18 years for (re-)immunisation

and

- ○ On immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response

or

- ○ With primary immune deficiencies

or

- ○ With HIV infection

or

- ○ With renal failure, or nephrotic syndrome

or

- ○ Who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant)

or

- ○ With cochlear implants or intracranial shunts

or

- ○ With cerebrospinal fluid leaks

or

- ○ Receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater

or

- ○ With chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy)

or

- ○ Pre term infants, born before 28 weeks gestation

or

- ○ With cardiac disease, with cyanosis or failure

or

- ○ With diabetes

or

- ○ With Down syndrome

or

- ○ Who are pre-or post-splenectomy, or with functional asplenia

INITIATION – Testing for primary immunodeficiency diseases
Prerequisites (tick box where appropriate)

- ○ For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician

I confirm that the above details are correct:

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Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Salmonella typhi vaccine

INITIATION

Prerequisites (tick box where appropriate)

○ For use during typhoid fever outbreaks

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Meningococcal B multicomponent vaccine

INITIATION – Primary immunisation for children up to 12 months of age
Re-assessment required after 3 doses
Prerequisites (tick boxes where appropriate)

- ○ Three doses for children up to 12 months of age (inclusive) for primary immunisation

or

- ○ Up to three doses (dependent on age at first dose) for a catch-up programme for children from 13 months to 59 months of age (inclusive) for primary immunisation, from 1 March 2023 to 31 August 2025

INITIATION – Person is one year of age or over
Prerequisites (tick boxes where appropriate)

- ○ Up to two doses and a booster every five years for patients pre- and post-splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post-solid organ transplant

or

- ○ Up to two doses for close contacts of meningococcal cases of any group

or

- ○ Up to two doses for person who has previously had meningococcal disease of any group

or

- ○ Up to two doses for bone marrow transplant patients

or

- ○ Up to two doses for person pre- and post-immunosuppression*

INITIATION – Person is aged between 13 and 25 years (inclusive)
Re-assessment required after 2 doses
Prerequisites (tick boxes where appropriate)

- ○ Person is aged between 13 and 25 years (inclusive)

and

- ○ Two doses for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, Youth Justice residences, or prisons

or

- ○ Two doses for individuals who turn 13 years of age while living in boarding school hostels

Note: *Immunosuppression due to corticosteroid or other immunosuppressive therapy must be for a period of greater than 28 days.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Hepatitis A vaccine

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ Two vaccinations for use in transplant patients

or

- ○ Two vaccinations for use in children with chronic liver disease

or

- ○ One dose of vaccine for close contacts of known hepatitis A cases

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Hepatitis B recombinant vaccine

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers

or

- ○ For children born to mothers who are hepatitis B surface antigen (HBsAg) positive

or

- ○ For children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination

or

- ○ For HIV positive patients

or

- ○ For hepatitis C positive patients

or

- ○ For patients following non-consensual sexual intercourse

or

- ○ For patients prior to planned immunosuppression for greater than 28 days

or

- ○ For patients following immunosuppression

or

- ○ For solid organ transplant patients

or

- ○ For post-haematopoietic stem cell transplant (HSCT) patients

or

- ○ Following needle stick injury

or

- ○ For dialysis patients

or

- ○ For liver or kidney transplant patients

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Hepatitis B recombinant vaccine

INITIATION

Prerequisites (tick boxes where appropriate)

- ○ For household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers

or

- ○ For children born to mothers who are hepatitis B surface antigen (HBsAg) positive

or

- ○ For children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination

or

- ○ For HIV positive patients

or

- ○ For hepatitis C positive patients

or

- ○ For patients following non-consensual sexual intercourse

or

- ○ For patients prior to planned immunosuppression for greater than 28 days

or

- ○ For patients following immunosuppression

or

- ○ For solid organ transplant patients

or

- ○ For post-haematopoietic stem cell transplant (HSCT) patients

or

- ○ Following needle stick injury

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Influenza vaccine Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)

INITIATION – People over 65

Prerequisites (tick box where appropriate)

- ○ The patient is 65 years of age or over

INITIATION – cardiovascular disease

Prerequisites (tick boxes where appropriate)

- ○ Ischaemic heart disease

or

- ○ Congestive heart failure

or

- ○ Rheumatic heart disease

or

- ○ Congenital heart disease

or

- ○ Cerebro-vascular disease

Note: hypertension and/or dyslipidaemia without evidence of end-organ disease is excluded from funding.

INITIATION – chronic respiratory disease

Prerequisites (tick boxes where appropriate)

- ○ Asthma, if on a regular preventative therapy

or

- ○ Other chronic respiratory disease with impaired lung function

Note: asthma not requiring regular preventative therapy is excluded from funding.

I confirm that the above details are correct:

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Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Influenza vaccine Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) *- continued*

INITIATION – Other conditions

Prerequisites (tick boxes where appropriate)

- ○ Diabetes

or

- ○ Chronic renal disease

or

- ○ Any cancer, excluding basal and squamous skin cancers if not invasive

or

- ○ Autoimmune disease

or

- ○ Immune suppression or immune deficiency

or

- ○ HIV

or

- ○ Transplant recipient

or

- ○ Neuromuscular and CNS diseases/ disorders

or

- ○ Haemoglobinopathies

or

- ○ Is a child on long term aspirin

or

- ○ Has a cochlear implant

or

- ○ Errors of metabolism at risk of major metabolic decompensation

or

- ○ Pre and post splenectomy

or

- ○ Down syndrome

or

- ○ Is pregnant

or

- ○ Is a child 4 years of age or under (inclusive) who has been hospitalised for respiratory illness or has a history of significant respiratory illness

or

- ○ Patients in a long-stay inpatient mental health care unit or who are compulsorily detained long-term in a forensic unit within a Public Hospital

INITIATION – Serious mental health conditions or addiction

Prerequisites (tick boxes where appropriate)

- ○ Schizophrenia

or

- ○ Major depressive disorder

or

- ○ Bipolar disorder

or

- ○ Schizoaffective disorder

or

- ○ Person is currently accessing secondary or tertiary mental health and addiction services

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Measles, mumps and rubella vaccine

INITIATION – first dose prior to 12 months
Re-assessment required after 3 doses
Prerequisites (tick boxes where appropriate)

- ○ For primary vaccination in children

or

- ○ For revaccination following immunosuppression

or

- ○ For any individual susceptible to measles, mumps or rubella

INITIATION – first dose after 12 months
Re-assessment required after 2 doses
Prerequisites (tick boxes where appropriate)

- ○ For primary vaccination in children

or

- ○ For revaccination following immunosuppression

or

- ○ For any individual susceptible to measles, mumps or rubella

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Poliomyelitis vaccine

INITIATION
Re-assessment required after 3 doses
Prerequisites (tick boxes where appropriate)

- ○ For partially vaccinated or previously unvaccinated individuals

or

- ○ For revaccination following immunosuppression

Note: Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Varicella vaccine [Chickenpox vaccine]

INITIATION – primary vaccinations
Re-assessment required after 1 dose
Prerequisites (tick boxes where appropriate)

- ○ Any infant born on or after 1 April 2016

or

- ○ For previously unvaccinated children turning 11 years old on or after 1 July 2017, who have not previously had a varicella infection (chickenpox)

INITIATION – other conditions
Re-assessment required after 2 doses
Prerequisites (tick boxes where appropriate)

for non-immune patients:

- ○ With chronic liver disease who may in future be candidates for transplantation

or

- ○ With deteriorating renal function before transplantation

or

- ○ Prior to solid organ transplant

or

- ○ Prior to any elective immunosuppression*

or

- ○ For post exposure prophylaxis who are immune competent inpatients

or

- ○ For patients at least 2 years after bone marrow transplantation, on advice of their specialist

or

- ○ For patients at least 6 months after completion of chemotherapy, on advice of their specialist

or

- ○ For HIV positive patients non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist

or

- ○ For patients with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella

or

- ○ For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella

or

- ○ For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella

Note: * immunosuppression due to steroid or other immunosuppressive therapy must be for a treatment period of greater than 28 days

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Human papillomavirus (6, 11, 16, 18, 31, 33, 45, 52 and 58) vaccine [HPV]

INITIATION – Children aged 14 years and under
Re-assessment required after 2 doses
Prerequisites (tick box where appropriate)

- ○ Children aged 14 years and under

INITIATION – other conditions
Prerequisites (tick boxes where appropriate)

- ○ Up to 3 doses for people aged 15 to 26 years inclusive

or

- ○ People aged 9 to 26 years inclusive

and

- ○ Up to 3 doses for confirmed HIV infection

or

- ○ Up to 3 doses people with a transplant (including stem cell)

or

- ○ Up to 4 doses for Post chemotherapy

INITIATION – Recurrent Respiratory Papillomatosis
Prerequisites (tick boxes where appropriate)

- ○ Maximum of two doses for children aged 14 years and under

or

- ○ Maximum of three doses for people aged 15 years and over

and

- ○ The person has recurrent respiratory papillomatosis

and

- ○ The person has not previously had an HPV vaccine

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Rotavirus oral vaccine

INITIATION
Re-assessment required after 2 doses
Prerequisites (tick boxes where appropriate)

- ○ First dose to be administered in infants aged under 14 weeks of age

and

- ○ No vaccination being administered to children aged 24 weeks or over

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Varicella zoster vaccine [shingles vaccine]

INITIATION – people aged 18 years and over (Shingrix)
Re-assessment required after 2 doses
Prerequisites (tick boxes where appropriate)

- ○ Pre- and post-haematopoietic stem cell transplant or cellular therapy

or

- ○ Pre- or post-solid organ transplant

or

- ○ Haematological malignancies

or

- ○ People living with poorly controlled HIV infection

or

- ○ Planned or receiving disease modifying anti-rheumatic drugs (DMARDs – targeted synthetic, biologic, or conventional synthetic) for polymyalgia rheumatica, systemic lupus erythematosus or rheumatoid arthritis

or

- ○ End stage kidney disease (CKD 4 or 5);

or

- ○ Primary immunodeficiency

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

COVID-19 vaccine

INITIATION – initial dose

Prerequisites (tick box where appropriate)

- ○ Up to three doses for previously unvaccinated children aged 6 months – 4 years at high risk of severe illness

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

COVID-19 vaccine

INITIATION – initial dose

Prerequisites (tick boxes where appropriate)

- ○ One dose for previously unvaccinated children aged 5-11 years old

or

- ○ Up to three doses for immunocompromised children aged 5-11 years old

I confirm that the above details are correct:

Signed: ..... Date: .....

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

COVID-19 vaccine

INITIATION – initial dose

Prerequisites (tick boxes where appropriate)

- ○ One dose for previously unvaccinated people aged 12-15 years old

or

- ○ Up to three doses for immunocompromised people aged 12-15 years old

or

- ○ Up to two doses for previously unvaccinated people 16-29 years old

or

- ○ Up to four doses for people aged 16-29 at high risk of severe illness

or

- ○ One dose for previously unvaccinated people aged 30 and older

INITIATION – additional dose

Prerequisites (tick box where appropriate)

- ○ One additional dose every 6 months for people aged 30 years and over, additional dose is given at least 6 months after last dose

CONTINUATION – additional dose

Prerequisites (tick box where appropriate)

- ○ One additional dose every 6 months for people aged 30 years and over, additional dose is given at least 6 months after last dose

I confirm that the above details are correct:

Signed: ..... Date: .....

Index of form numbers

Index of titles