

**SPECIAL AUTHORITY FORMS**  
**January 2025**

Therapeutic Groups

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## THE SPECIAL AUTHORITY SYSTEM

Special Authority is an application process in which a prescriber requests government subsidy for a particular person.

### Criteria

The criteria for approval of Special Authority applications are included below each pharmaceutical listing. For some Special Authority pharmaceuticals, not all indications listed on the data sheets are subsidised. Criteria for each Special Authority pharmaceutical are updated regularly, based on the decision criteria of Pharmac. The appropriateness of the listing of a pharmaceutical in the Special Authority category will also be regularly reviewed. Applications for inclusion of further pharmaceuticals in the Special Authority category will generally be made by a pharmaceutical supplier.

### Applications from Specialists

“Specialist” means, a doctor who holds a current annual practising certificate and who satisfies the criteria set out below.

- a. The doctor’s name appears in the Vocational Register of medical practitioners in accordance with Section 21 and 22 of the Medical Practitioners Act 1995 and who is making the application in the course of practising in that area of medicine; and the doctor’s vocational branch or sub-branch is one of those listed below:
  - anaesthetics
  - cardiothoracic surgery
  - dermatology
  - diagnostic radiology
  - emergency medicine
  - general surgery
  - internal medicine
  - neurosurgery
  - obstetrics and gynaecology
  - occupational medicine
  - ophthalmology
  - otolaryngology head and neck surgery
  - orthopaedic surgery
  - paediatric surgery
  - paediatrics
  - pathology
  - plastic and reconstructive surgery
  - psychological medicine or psychiatry
  - public health medicine
  - radiation oncology
  - rehabilitation medicine
  - urology and venereology
- b. The doctor is recognised by the Ministry of Health as a specialist for the purposes of the Pharmaceutical Schedule and receives remuneration from a Health NZ Hospital at a level which that Health NZ Hospital considers appropriate for specialists and who has written that Prescription in the course of practising in that area of medicine
- c. The doctor is recognised by the Ministry of Health as a specialist in relation to a particular area of medicine for the purpose of writing Prescriptions and who has written the Prescription in the course of practising in that area of medicine.
- d. The doctor writes the Prescription on Health NZ Hospital stationery and is appropriately authorised by the relevant Health NZ Hospital to do so.

### Approval

Special Authority applications are administered by the Ministry of Health. They were formerly administered by Health Payments, Agreements and Compliance (HealthPAC), a division of the Ministry of Health. All applications should be sent, in writing, to:

Ministry of Health, Private Bag 3015, WANGANUI

[customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

For inquiries, please call the Contact Centre on, free phone 0800 243 666

Each application must include:

- name and date of birth of the patient (codes for AIDS patients’ applications)
- diagnosis and brief clinical details
- name of the medicine required, the form and strength of the medicine
- duration of the course of treatment
- alternative therapies that have been tried

The application must:

- be signed by the practitioner
- include the practitioner’s printed name and address
- show the practitioner’s Medical Council registration number
- provide evidence of the criteria as per Special Authority conditions for medicine applied for

### Subsidy

Once approved, health providers can obtain the Special Authority approval details for prescribing and dispensing purposes by calling the Contact Centre on 0800 243 666.

Specialists who make an application must communicate the valid authority number to the prescriber who will be writing the prescriptions.

The authority number can provide access to subsidy, additional subsidy, or waive certain restrictions otherwise present on the pharmaceutical.

Some approvals are dependent on the availability of funding.

## Panel Approvals

Access to subsidy for the following products must be approved by a panel of clinicians  
Applications to be made on the approved forms which are available from the co-ordinator:

Panel Co-ordinator  
Pharmac  
PO Box 10 254 Wellington  
Phone: 04 460 4990 Facsimile: 04 460 4995  
E-mail: ECPanel@Pharmac.govt.nz

<b>Product (Form No)</b>	<b>Panel</b>
Dulaglutide (SA2338)	PHARMAC
Ledipasvir with sofosbuvir (SA1605)	Hepatitis C Treatment Panel (HepCTP)
Liraglutide (SA2339)	PHARMAC

## **Alimentary Tract and Metabolism**

**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER** Reg No: .....

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**Budesonide - Cap 3 mg Controlled Release**

**Initial application — Crohn's disease**  
Applications from any relevant practitioner. Approvals valid for 6 months.  
**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)

**Initial application — collagenous and lymphocytic colitis (microscopic colitis)**  
Applications from any relevant practitioner. Approvals valid for 6 months.  
**Prerequisites**(tick box where appropriate)

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

**Initial application — gut Graft versus Host disease**  
Applications from any relevant practitioner. Approvals valid for 6 months.  
**Prerequisites**(tick box where appropriate)

Patient has a gut Graft versus Host disease following allogenic bone marrow transplantation\*  
Note: Indication marked with \* is an unapproved indication.

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: ..... Date: .....  
Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Budesonide - Cap 3 mg Controlled Release - continued**

**Initial application — non-cirrhotic autoimmune hepatitis**  
Applications from any relevant practitioner. Approvals valid for 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: Indication marked with \* is an unapproved indication.

**Renewal**

Current approval Number (if known):.....  
Applications from any relevant practitioner. Approvals valid for 6 months.  
**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

**Renewal — non-cirrhotic autoimmune hepatitis**

Current approval Number (if known):.....  
Applications from any relevant practitioner. Approvals valid for 6 months.  
**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

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**Glyceryl trinitrate Oint 0.2%**

<p><b>Initial application</b> Applications from any relevant practitioner. Approvals valid without further renewal unless notified.</p> <p><b>Prerequisites</b>(tick box where appropriate)</p> <p><input type="checkbox"/> The patient has a chronic anal fissure that has persisted for longer than three weeks</p>
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I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Rifaximin**

**Initial application**

Applications only from a gastroenterologist, hepatologist or Practitioner on the recommendation of a gastroenterologist or hepatologist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

The patient has hepatic encephalopathy despite an adequate trial of maximum tolerated doses of lactulose

**Renewal**

Current approval Number (if known):.....

Applications only from a gastroenterologist, hepatologist or Practitioner on the recommendation of a gastroenterologist or hepatologist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**Diazoxide**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

Used for the treatment of confirmed hypoglycaemia caused by hyperinsulinism

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

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**Empagliflozin; Empagliflozin with metformin hydrochloride**

**Initial application — heart failure reduced ejection fraction**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**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

**Initial application — Type 2 Diabetes**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

Patient has previously received 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/1.73m<sup>2</sup> 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.

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**Insulin pump with algorithm**

**Initial application — type 1 diabetes**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has type 1 diabetes
- or
- The patient has permanent neonatal diabetes or specific monogenic diabetes subtypes with insulin deficiency, considered by the treating endocrinologist as likely to benefit
- or
- The patient has Type 3c diabetes considered by the treating endocrinologist as likely to benefit (Type 3c diabetes includes insulin deficiency due to pancreatectomy, insulin deficiency secondary to cystic fibrosis or pancreatitis)
- or
- The patient has atypical inherited forms of diabetes

and

Patient has been evaluated by a diabetes multidisciplinary team for their suitability for insulin pump therapy

and

In the opinion of the treating relevant practitioner the patient would benefit from an Automated Insulin Delivery (AID) system

**Renewal — type 1 diabetes**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

- The patient is continuing to derive benefit according to the treatment plan agreed at induction

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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**Insulin Pump Consumables**

**Initial application — type 1 diabetes**

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The patient has type 1 diabetes <b>or</b> <input type="checkbox"/> The patient has permanent neonatal diabetes or specific monogenic diabetes subtypes with insulin deficiency, considered by the treating endocrinologist as likely to benefit <b>or</b> <input type="checkbox"/> The patient has Type 3c diabetes considered by the treating endocrinologist as likely to benefit (Type 3c diabetes includes insulin deficiency due to pancreatectomy, insulin deficiency secondary to cystic fibrosis or pancreatitis) <b>or</b> <input type="checkbox"/> The patient has atypical inherited forms of diabetes
<b>and</b>
<input type="checkbox"/> Patient has been evaluated by a diabetes multidisciplinary team for their suitability for insulin pump therapy
<b>and</b>
<input type="checkbox"/> In the opinion of the treating relevant practitioner the patient would benefit from an Automated Insulin Delivery (AID) system

**Renewal — type 1 diabetes**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

The patient is continuing to derive benefit according to the treatment plan agreed at induction

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**Continuous glucose monitor (standalone)**

**Initial application — type 1 diabetes**

Applications from any relevant practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

<p><input type="checkbox"/> The patient has type 1 diabetes</p> <p><b>or</b></p> <p><input type="checkbox"/> The patient has permanent neonatal diabetes or specific monogenic diabetes subtypes with insulin deficiency, considered by the treating endocrinologist or relevant secondary health care professional as practicable, as likely to benefit</p> <p><b>or</b></p> <p><input type="checkbox"/> The patient has Type 3c diabetes considered by the treating endocrinologist or relevant secondary health care professional as practicable, as likely to benefit (Type 3c diabetes includes insulin deficiency due to pancreatectomy, insulin deficiency secondary to cystic fibrosis or pancreatitis)</p> <p><b>or</b></p> <p><input type="checkbox"/> The patient has atypical inherited forms of diabetes</p>
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**Renewal — type 1 diabetes**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

The patient is continuing to derive benefit according to the treatment plan agreed at induction

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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**Continuous glucose monitor (interoperable)**

**Initial application — type 1 diabetes**

Applications from any relevant practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

- The patient has type 1 diabetes
- or
- The patient has permanent neonatal diabetes or specific monogenic diabetes subtypes with insulin deficiency, considered by the treating endocrinologist or relevant secondary health care professional as practicable, as likely to benefit
- or
- The patient has Type 3c diabetes considered by the treating endocrinologist or relevant secondary health care professional as practicable, as likely to benefit (Type 3c diabetes includes insulin deficiency due to pancreatectomy, insulin deficiency secondary to cystic fibrosis or pancreatitis)
- or
- The patient has atypical inherited forms of diabetes

and

- In the opinion of the treating relevant practitioner the patient would benefit from an Automated Insulin Delivery (AID) system

**Renewal — type 1 diabetes**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

- The patient is continuing to derive benefit according to the treatment plan agreed at induction

I confirm the above details are correct and that in signing this form I understand I may be audited.

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Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Ursodeoxycholic Acid**

**Initial application — Alagille syndrome or progressive familial intrahepatic cholestasis**  
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.  
**Prerequisites**(tick boxes where appropriate)

Patient has been diagnosed with Alagille syndrome  
or  
 Patient has progressive familial intrahepatic cholestasis

**Initial application — Chronic severe drug induced cholestatic liver injury**  
Applications from any relevant practitioner. Approvals valid for 3 months.  
**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

**Initial application — Primary biliary cholangitis**  
Applications from any relevant practitioner. Approvals valid for 6 months.  
**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)

**Initial application — Pregnancy**  
Applications from any relevant practitioner. Approvals valid for 6 months.  
**Prerequisites**(tick box where appropriate)

The patient diagnosed with cholestasis of pregnancy

**Initial application — Haematological Transplant**  
Applications from any relevant practitioner. Approvals valid for 6 months.  
**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

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Ursodeoxycholic Acid** - *continued*

**Initial application — Total parenteral nutrition induced cholestasis**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Paediatric patient has developed abnormal liver function as indicated on testing which is likely to be induced by Total Parenteral Nutrition (TPN) <b>and</b> <input type="checkbox"/> Liver function has not improved with modifying the TPN composition
--

**Renewal — Chronic severe drug induced cholestatic liver injury**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

The patient continues to benefit from treatment

**Renewal — Pregnancy/Primary biliary cholangitis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

**Renewal — Total parenteral nutrition induced cholestasis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

The paediatric patient continues to require TPN and who is benefiting from treatment, defined as a sustained improvement in bilirubin levels

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**Methylnaltrexone bromide**

**Initial application — Opioid induced constipation**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The patient is receiving palliative care
<b>and</b>
<input type="checkbox"/> Oral and rectal treatments for opioid induced constipation are ineffective
<b>or</b>
<input type="checkbox"/> Oral and rectal treatments for opioid induced constipation are unable to be tolerated

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Sodium picosulfate**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient is a child with problematic constipation despite an adequate trial of other oral pharmacotherapies including macrogol where practicable
<b>and</b>	
<input type="checkbox"/>	The patient would otherwise require a high-volume bowel cleansing preparation or hospital admission

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

<input type="checkbox"/>	The treatment remains appropriate and the patient is benefiting from treatment
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**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**Galsulfase**

**Initial application**

Applications only from a metabolic physician. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has been diagnosed with mucopolysaccharidosis VI
<b>and</b>	
<input type="checkbox"/>	Diagnosis confirmed by demonstration of N-acetyl-galactosamine-4-sulfatase (arylsulfatase B) deficiency by either enzyme activity assay in leukocytes or skin fibroblasts
<b>or</b>	
<input type="checkbox"/>	Detection of two disease causing mutations and patient has a sibling who is known to have mucopolysaccharidosis VI

**Renewal**

Current approval Number (if known):.....

Applications only from a metabolic physician. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The treatment remains appropriate for the patient and the patient is benefiting from treatment
<b>and</b>	
<input type="checkbox"/>	Patient has not had severe infusion-related adverse reactions which were not preventable by appropriate pre-medication and/or adjustment of infusion rates
<b>and</b>	
<input type="checkbox"/>	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)
<b>and</b>	
<input type="checkbox"/>	Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT

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**Sodium phenylbutyrate**

**Initial application**

Applications only from a metabolic physician. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

The patient has a diagnosis of a urea cycle disorder involving a deficiency of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase

**Renewal**

Current approval Number (if known):.....

Applications only from a metabolic physician. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

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**Sodium benzoate**

**Initial application**

Applications only from a metabolic physician. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

The patient has a diagnosis of a urea cycle disorder

**Renewal**

Current approval Number (if known):.....

Applications only from a metabolic physician. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

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**Alglucosidase Alfa**

**Initial application**

Applications only from a metabolic physician. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal**

Current approval Number (if known):.....

Applications only from a metabolic physician. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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

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**Idursulfase**

**Initial application**

Applications only from a metabolic physician. Approvals valid for 24 weeks.

**Prerequisites**(tick boxes where appropriate)

- The patient has been diagnosed with Hunter Syndrome (mucopolysaccharidosis 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

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**Laronidase**

**Initial application**

Applications only from a metabolic physician. Approvals valid for 24 weeks.

**Prerequisites**(tick boxes where appropriate)

The patient has been diagnosed with Hurler Syndrome (mucopolysaccharidosis 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

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**Betaine**

**Initial application**

Applications only from a metabolic physician. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The patient has a confirmed diagnosis of homocystinuria <b>and</b> <input type="checkbox"/> A cystathionine beta-synthase (CBS) deficiency <b>or</b> <input type="checkbox"/> A 5,10-methylene-tetrahydrofolate reductase (MTHFR) deficiency <b>or</b> <input type="checkbox"/> A disorder of intracellular cobalamin metabolism <b>and</b> <input type="checkbox"/> An appropriate homocysteine level has not been achieved despite a sufficient trial of appropriate vitamin supplementation
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**Renewal**

Current approval Number (if known):.....

Applications only from a metabolic physician. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

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### Saproterin dihydrochloride

#### Initial application

Applications only from a metabolic physician. Approvals valid for 1 month.

**Prerequisites**(tick boxes where appropriate)

- Patient has phenylketonuria (PKU) and is pregnant or actively planning to become pregnant
- and  Treatment with saproterin is required to support management of PKU during pregnancy
- and  Saproterin to be administered at doses no greater than a total daily dose of 20 mg/kg
- and  Saproterin to be used alone or in combination with PKU dietary management
- and  Total treatment duration with saproterin will not exceed 22 months for each pregnancy (includes time for planning and becoming pregnant) and treatment will be stopped after delivery

#### Renewal

Current approval Number (if known):.....

Applications only from a metabolic physician or any relevant practitioner on the recommendation of a metabolic physician. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- Following the initial one-month approval, the patient has demonstrated an adequate response to a 2 to 4 week trial of saproterin 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 saproterin and maintained adequate phenylalanine levels to support management of PKU during pregnancy
- and  Patient continues to be pregnant and treatment with saproterin will not continue after delivery
- or  Patient is actively planning a pregnancy and this is the first renewal for treatment with saproterin
- or  Treatment with saproterin is required for a second or subsequent pregnancy to support management of their PKU during pregnancy
- and  Saproterin to be administered at doses no greater than a total daily dose of 20 mg/kg
- and  Saproterin to be used alone or in combination with PKU dietary management
- and  Total treatment duration with saproterin will not exceed 22 months for each pregnancy (includes time for planning and becoming pregnant) and treatment will be stopped after delivery

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Coenzyme Q10**

**Initial application**

Applications only from a metabolic physician. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

Patient has a suspected inborn error of metabolism that may respond to coenzyme Q10 supplementation

**Renewal**

Current approval Number (if known):.....

Applications only from a metabolic physician. Approvals valid for 24 months.

**Prerequisites**(tick boxes where appropriate)

<p><input type="checkbox"/> The patient has a confirmed diagnosis of an inborn error of metabolism that responds to coenzyme Q10 supplementation</p> <p><b>and</b></p> <p><input type="checkbox"/> The treatment remains appropriate and the patient is benefiting from treatment</p>
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I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Levocarnitine**

**Initial application**

Applications only from a metabolic physician. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

Patient has a suspected inborn error of metabolism that may respond to carnitine supplementation

**Renewal**

Current approval Number (if known):.....

Applications only from a metabolic physician. Approvals valid for 24 months.

**Prerequisites**(tick boxes where appropriate)

<p><input type="checkbox"/></p> <p><b>and</b></p> <p><input type="checkbox"/></p>	<p>The patient has a confirmed diagnosis of an inborn error of metabolism that responds to carnitine supplementation</p> <p>The treatment remains appropriate and the patient is benefiting from treatment</p>
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**Riboflavin**

**Initial application**

Applications only from a metabolic physician or neurologist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

Patient has a suspected inborn error of metabolism that may respond to riboflavin supplementation

**Renewal**

Current approval Number (if known):.....

Applications only from a metabolic physician or neurologist. Approvals valid for 24 months.

**Prerequisites**(tick boxes where appropriate)

<p><input type="checkbox"/></p> <p><b>and</b></p> <p><input type="checkbox"/></p>	<p>The patient has a confirmed diagnosis of an inborn error of metabolism that responds to riboflavin supplementation</p> <p>The treatment remains appropriate and the patient is benefiting from treatment</p>
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**Arginine**

**Initial application**

Applications only from a metabolic physician. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

Patient has a suspected inborn error of metabolism that may respond to arginine supplementation

**Renewal**

Current approval Number (if known):.....

Applications only from a metabolic physician. Approvals valid for 24 months.

**Prerequisites**(tick boxes where appropriate)

The patient has a confirmed diagnosis of an inborn error of metabolism that responds to arginine supplementation

**and**

The treatment remains appropriate and the patient is benefiting from treatment

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

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**Taurine**

**Initial application**

Applications only from a metabolic physician. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

Patient has a suspected specific mitochondrial disorder that may respond taurine supplementation

**Renewal**

Current approval Number (if known):.....

Applications only from a metabolic physician. Approvals valid for 24 months.

**Prerequisites**(tick boxes where appropriate)

The patient has confirmed diagnosis of a specific mitochondrial disorder which responds to taurine supplementation  
**and**  
 The treatment remains appropriate and the patient is benefiting from treatment

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

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**Trintine**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has confirmed Wilson disease
<b>and</b>	
<input type="checkbox"/>	Treatment with D-penicillamine has been trialled and discontinued because the person has experienced intolerable side effects or has not received sufficient benefit
<b>and</b>	
<input type="checkbox"/>	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 the above details are correct and that in signing this form I understand I may be audited.

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

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**Taliglucerase alfa**

**Initial application**

Applications only from a metabolic physician. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal**

Current approval Number (if known):.....

Applications only from a metabolic physician or any relevant practitioner on the recommendation of a metabolic physician. Approvals valid for 3 years.

**Prerequisites**(tick boxes where appropriate)

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**

Radiological (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 the above details are correct and that in signing this form I understand I may be audited.**

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**Vitabdeck**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has cystic fibrosis with pancreatic insufficiency
or
<input type="checkbox"/> Patient is an infant or child with liver disease or short gut syndrome
or
<input type="checkbox"/> Patient has severe malabsorption syndrome

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Multivitamins** (Paediatric Seravit)

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The patient has inborn errors of metabolism

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

Patient has had a previous approval for multivitamins

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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**Multivitamin renal** (Clinicians Renal Vit)

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<b>or</b>	<input type="checkbox"/> The patient has chronic kidney disease and is receiving either peritoneal dialysis or haemodialysis  <input type="checkbox"/> The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of < 15 ml/min/1.73 m <sup>2</sup> body surface area (BSA)
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Signed: ..... Date: .....

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**Ferric carboxymaltose**

**Initial application — Anaemia**

Applications from any relevant practitioner. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has been diagnosed with anaemia
<b>and</b>
<input type="checkbox"/> Serum ferritin level is 20 mcg/L or less
<b>or</b>
<input type="checkbox"/> Serum ferritin is between 20 and 50 mcg/L
<b>and</b>
<input type="checkbox"/> C-Reactive Protein (CRP) is at least 5 mg/L
<b>or</b>
<input type="checkbox"/> Patient has chronic inflammatory disease with symptoms of anaemia despite normal iron levels
<b>and</b>
<input type="checkbox"/> Oral iron treatment has proven ineffective
<b>or</b>
<input type="checkbox"/> Oral iron treatment has resulted in dose-limiting intolerance
<b>or</b>
<input type="checkbox"/> Rapid correction of anaemia is required

**Renewal — Anaemia**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient continues to have anaemia with a serum ferritin level of 20 mcg/L, or less or between 20 and 50 mcg/L with CRP of at least 5 mg/L, or has chronic inflammatory disease with symptoms of anaemia despite normal iron levels
<b>and</b>
<input type="checkbox"/> A trial (or re-trial) with oral iron is clinically inappropriate

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**Ferric carboxymaltose** - *continued*

**Initial application — iron deficiency anaemia**

Applications only from an internal medicine physician, obstetrician, gynaecologist, anaesthetist or medical practitioner on the recommendation of an internal medicine physician, obstetrician, gynaecologist or anaesthetist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has been diagnosed with iron-deficiency anaemia
<b>and</b>	
<input type="checkbox"/>	Patient has been compliant with oral iron treatment and treatment has proven ineffective
<b>or</b>	
<input type="checkbox"/>	Treatment with oral iron has resulted in dose-limiting intolerance
<b>or</b>	
<input type="checkbox"/>	Patient has symptomatic heart failure, chronic kidney disease stage 3 or more or active inflammatory bowel disease and a trial of oral iron is unlikely to be effective
<b>or</b>	
<input type="checkbox"/>	Rapid correction of anaemia is required

**Renewal — iron deficiency anaemia**

Current approval Number (if known):.....

Applications only from an internal medicine physician, obstetrician, gynaecologist, anaesthetist or medical practitioner on the recommendation of an internal medicine physician, obstetrician, gynaecologist or anaesthetist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient continues to have iron-deficiency anaemia
<b>and</b>	
<input type="checkbox"/>	A re-trial with oral iron is clinically inappropriate

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**Blood and Blood Forming Organs**



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**Hypoplastic and Haemolytic**

**Initial application — chronic renal failure**

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient in chronic renal failure
<b>and</b>	
<input type="checkbox"/>	Haemoglobin is less than or equal to 100g/L
<b>and</b>	
<input type="checkbox"/>	Patient does not have diabetes mellitus
<b>and</b>	
<input type="checkbox"/>	Glomerular filtration rate is less than or equal to 30ml/min
<b>or</b>	
<input type="checkbox"/>	Patient has diabetes mellitus
<b>and</b>	
<input type="checkbox"/>	Glomerular filtration rate is less than or equal to 45ml/min
<b>or</b>	
<input type="checkbox"/>	Patient is on haemodialysis or peritoneal dialysis

**Initial application — myelodysplasia**

Applications from any specialist. Approvals valid for 2 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has a confirmed diagnosis of myelodysplasia (MDS)*
<b>and</b>	
<input type="checkbox"/>	Has had symptomatic anaemia with haemoglobin < 100g/L and is red cell transfusion-dependent
<b>and</b>	
<input type="checkbox"/>	Patient has very low, low or intermediate risk MDS based on the WHO classification based prognostic scoring system for myelodysplastic syndrome (WPSS)
<b>and</b>	
<input type="checkbox"/>	Other causes of anaemia such as B12 and folate deficiency have been excluded
<b>and</b>	
<input type="checkbox"/>	Patient has a serum epoetin level of < 500 IU/L
<b>and</b>	
<input type="checkbox"/>	The minimum necessary dose of epoetin would be used and will not exceed 80,000 iu per week

Note: Indication marked with \* is an unapproved indication

**Renewal — chronic renal failure**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

<input type="checkbox"/>	The treatment remains appropriate and the patient is benefiting from treatment
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**Hypoplastic and Haemolytic** - *continued*

**Renewal — myelodysplasia**

Current approval Number (if known):.....

Applications from any specialist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient's transfusion requirement continues to be reduced with erythropoietin treatment
<b>and</b>	
<input type="checkbox"/>	Transformation to acute myeloid leukaemia has not occurred
<b>and</b>	
<input type="checkbox"/>	The minimum necessary dose of epoetin would be used and will not exceed 80,000 iu per week

Note: Indication marked with \* is an unapproved indication

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**Eltrombopag**

**Initial application — idiopathic thrombocytopenic purpura - post-splenectomy**

Applications only from a haematologist. Approvals valid for 6 weeks.

**Prerequisites**(tick boxes where appropriate)

Patient has had a splenectomy  
**and**  
 Two immunosuppressive therapies have been trialed 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

**Initial application — idiopathic thrombocytopenic purpura - preparation for splenectomy**

Applications only from a haematologist. Approvals valid for 6 weeks.

**Prerequisites**(tick box where appropriate)

The patient requires eltrombopag treatment as preparation for splenectomy

**Initial application — idiopathic thrombocytopenic purpura contraindicated to splenectomy**

Applications only from a haematologist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

Patient has a significant and well-documented contraindication to splenectomy for clinical reasons  
**and**  
 Two immunosuppressive therapies have been trialed 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

**Initial application — severe aplastic anaemia**

Applications only from a haematologist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

Two immunosuppressive therapies have been trialed 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

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**Eltrombopag - continued**

**Renewal — idiopathic thrombocytopenic purpura - post-splenectomy**

Current approval Number (if known):.....

Applications only from a haematologist. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

- 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.

**Renewal — idiopathic thrombocytopenic purpura contraindicated to splenectomy**

Current approval Number (if known):.....

Applications only from a haematologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Renewal — severe aplastic anaemia**

Current approval Number (if known):.....

Applications only from a haematologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- 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

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**Emicizumab**

**Initial application — Severe Haemophilia A with or without FVIII inhibitors**

Applications only from a haematologist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<p><b>and</b></p>	<input type="checkbox"/> Patient has severe congenital haemophilia A with a severe bleeding phenotype (endogenous factor VIII activity less than or equal to 2%)
	<input type="checkbox"/> 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 the above details are correct and that in signing this form I understand I may be audited.

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**Ticagrelor**

**Initial application — acute coronary syndrome**  
Applications from any relevant practitioner. Approvals valid for 12 months.  
**Prerequisites**(tick boxes where appropriate)

Patient has recently (within the last 60 days) been diagnosed with an ST-elevation or a non-ST-elevation acute coronary syndrome  
and  
 Fibrinolytic therapy has not been given in the last 24 hours and is not planned

**Initial application — thrombosis prevention neurological stenting**  
Applications from any relevant practitioner. Approvals valid for 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

**Initial application — Percutaneous coronary intervention with stent deployment**  
Applications from any relevant practitioner. Approvals valid for 6 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\*\*

**Initial application — Stent thrombosis**  
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.  
**Prerequisites**(tick box where appropriate)

Patient has experienced cardiac stent thrombosis whilst on clopidogrel

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**Ticagrelor** - *continued*

**Renewal — subsequent acute coronary syndrome**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<p><input type="checkbox"/> Patient has recently (within the last 60 days) been diagnosed with an ST-elevation or a non-ST-elevation acute coronary syndrome</p> <p><b>and</b></p> <p><input type="checkbox"/> Fibrinolytic therapy has not been given in the last 24 hours and is not planned</p>
--

**Renewal — thrombosis prevention neurological stenting**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<p><input type="checkbox"/> Patient is continuing to benefit from treatment</p> <p><b>and</b></p> <p><input type="checkbox"/> Treatment continues to be clinically appropriate</p>
--

**Renewal — Percutaneous coronary intervention with stent deployment**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<p><input type="checkbox"/> Patient has undergone percutaneous coronary intervention</p> <p><b>and</b></p> <p><input type="checkbox"/> Patient has had a stent deployed in the previous 4 weeks</p> <p><b>and</b></p> <p><input type="checkbox"/> Patient is clopidogrel-allergic**</p>
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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.

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**Enoxaparin sodium**

**Initial application — Pregnancy, Malignancy or Haemodialysis**  
Applications from any relevant practitioner. Approvals valid for 1 year.  
**Prerequisites**(tick boxes where appropriate)

- Low molecular weight heparin treatment is required during a patients pregnancy
- or
- For the treatment of venous thromboembolism where the patient has a malignancy
- or
- For the prevention of thrombus formation in the extra-corporeal circulation during haemodialysis

**Initial application — Venous thromboembolism other than in pregnancy or malignancy**  
Applications from any relevant practitioner. Approvals valid for 1 month.  
**Prerequisites**(tick boxes where appropriate)

- For the short-term treatment of venous thromboembolism prior to establishing a therapeutic level of oral anti-coagulant treatment
- or
- For the prophylaxis and treatment of venous thromboembolism in high risk surgery
- or
- To enable cessation/re-establishment of existing oral anticoagulant treatment pre/post surgery
- or
- For the prophylaxis and treatment of venous thromboembolism in Acute Coronary Syndrome surgical intervention
- or
- To be used in association with cardioversion of atrial fibrillation

**Initial application — Short-term use during treatment of COVID-19 with nirmatrelvir with ritonavir**  
Applications from any relevant practitioner. Approvals valid for 2 weeks.  
**Prerequisites**(tick boxes where appropriate)

- Patient is receiving an anticoagulation treatment that has drug/drug interactions with ritonavir that increases risk of bleeding
- and
- Patient meets the Access Criteria for COVID-19 antivirals published on the Pharmac website\*
- and
- Other antiviral treatments for COVID-19 have been considered and are not clinically suitable options

**Renewal — Pregnancy, Malignancy or Haemodialysis**  
Current approval Number (if known):.....  
Applications from any relevant practitioner. Approvals valid for 1 year.  
**Prerequisites**(tick boxes where appropriate)

- Low molecular weight heparin treatment is required during a patient's pregnancy
- or
- For the treatment of venous thromboembolism where the patient has a malignancy
- or
- For the prevention of thrombus formation in the extra-corporeal circulation during haemodialysis

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**Enoxaparin sodium** - *continued*

**Renewal — Venous thromboembolism other than in pregnancy or malignancy**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 1 month.

**Prerequisites**(tick box where appropriate)

Low molecular weight heparin treatment or prophylaxis is required for a second or subsequent event (surgery, ACS, cardioversion, or prior to oral anti-coagulation)

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**Filgrastim**

**Initial application**

Applications only from a relevant specialist, vocationally registered general practitioner or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk greater than or equal to 20%*)
or	
<input type="checkbox"/>	Peripheral blood stem cell mobilisation in patients undergoing haematological transplantation
or	
<input type="checkbox"/>	Peripheral blood stem cell mobilisation or bone marrow donation from healthy donors for transplantation
or	
<input type="checkbox"/>	Treatment of severe chronic neutropenia (ANC < 0.5 ×10 <sup>9</sup> /L)
or	
<input type="checkbox"/>	Treatment of drug-induced prolonged neutropenia (ANC < 0.5 ×10 <sup>9</sup> /L)

Note: \*Febrile neutropenia risk greater than or equal to 20% after taking into account other risk factors as defined by the European Organisation for Research and Treatment of Cancer (EORTC) guidelines.

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Pegfilgrastim**

**Initial application**

Applications only from a relevant specialist, vocationally registered general practitioner or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

Used 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.

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**Cardiovascular System**

**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER** Reg No: .....

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**Sacubitril with valsartan**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**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

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**Midodrine**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

Patient has disabling orthostatic hypotension not due to drugs

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Propranolol**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<p><b>or</b></p>	<input type="checkbox"/> For the treatment of a child under 12 years with an haemangioma causing functional impairment (not for cosmetic reasons only)
	<input type="checkbox"/> For the treatment of a child under 12 years with cardiac arrhythmias or congenital cardiac abnormalities

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<p><b>or</b></p>	<input type="checkbox"/> For the treatment of a child under 12 years with an haemangioma causing functional impairment (not for cosmetic reasons only)
	<input type="checkbox"/> For the treatment of a child under 12 years with cardiac arrhythmias or congenital cardiac abnormalities

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Eplerenone**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has heart failure with ejection fraction less than 40%
<b>and</b>
<input type="checkbox"/> Patient is intolerant to optimal dosing of spironolactone
<b>or</b>
<input type="checkbox"/> Patient has experienced a clinically significant adverse effect while on optimal dosing of spironolactone

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Tolvaptan**

**Initial application — autosomal dominant polycystic kidney disease**

Applications only from a renal physician or any relevant practitioner on the recommendation of a renal physician. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- 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<sup>2</sup> 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<sup>2</sup> 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<sup>2</sup> per year over a five-year period

**Renewal — autosomal dominant polycystic kidney disease**

Current approval Number (if known):.....

Applications only from a renal physician or any relevant practitioner on the recommendation of a renal physician. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- Patient has not developed end-stage renal disease, defined as an eGFR of less than 15 mL/min/1.73 m<sup>2</sup>
- and**
- Patient has not undergone a kidney transplant

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**Rosuvastatin**

**Initial application — cardiovascular disease risk**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**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

**Initial application — familial hypercholesterolemia**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**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

**Initial application — established cardiovascular disease**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**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

**Initial application — recurrent major cardiovascular events**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**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

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**Hydralazine**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<p><b>or</b></p>	<input type="checkbox"/> For the treatment of refractory hypertension  <input type="checkbox"/> 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
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**Bosentan**

**Initial application — PAH monotherapy**

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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<sup>-5</sup>)  
**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 the above details are correct and that in signing this form I understand I may be audited.

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**Bosentan** - continued

**Initial application — PAH dual therapy**

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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<sup>-5</sup>)

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 the above details are correct and that in signing this form I understand I may be audited.

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**Bosentan** - continued

**Initial application — PAH triple therapy**

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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<sup>-5</sup>)

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 the above details are correct and that in signing this form I understand I may be audited.

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

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**Bosentan** - continued

<p><b>Renewal</b></p> <p>Current approval Number (if known):.....</p> <p>Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 2 years.</p> <p><b>Prerequisites</b>(tick box where appropriate)</p> <p><input type="checkbox"/> Patient is continuing to derive benefit from bosentan treatment according to a validated PAH risk stratification tool**</p>
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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 the above details are correct and that in signing this form I understand I may be audited.

Signed: ..... Date: .....  
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**Ambrisentan**

**Initial application — PAH monotherapy**

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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<sup>-5</sup>)

**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 2022 (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 the above details are correct and that in signing this form I understand I may be audited.**

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

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**Ambrisentan** - continued

**Initial application — PAH dual therapy**

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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<sup>-5</sup>)  
**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 2022 (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 a PAH monotherapy (sildenafil or bosentan) for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool\*\*  
**or**  Patient has tried PAH dual therapy including bosentan and has experienced intolerable side effects on bosentan

**and**

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

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**Ambrisentan** - continued

**Initial application — PAH triple therapy**

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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<sup>-5</sup>)

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 2022 (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

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**Ambrisentan** - *continued*

**Renewal**

Current approval Number (if known):.....

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

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 the above details are correct and that in signing this form I understand I may be audited.

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**Sildenafil (Vedafil)**

**Initial application — Raynaud’s Phenomenon\***

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**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 (avoidance of cold exposure, sufficient protection, smoking cessation support, avoidance of sympathomimetic drugs)
- and  Patient is being treated with calcium channel blockers and nitrates (or these are contraindicated/not tolerated)

**Initial application — Pulmonary arterial hypertension\***

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

- 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 greater than 160 International Units (dyn s cm<sup>-5</sup>)
  - 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 the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT NHI:</b> .....	<b>REFERRER</b> Reg No: .....
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**Sildenafil (Vedafil) - continued**

**Initial application — erectile dysfunction due to spinal cord injury**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<b>and</b>	<input type="checkbox"/> Patient has a documented history of traumatic or non-traumatic spinal cord injury
	<input type="checkbox"/> Patient has erectile dysfunction secondary to spinal cord injury requiring pharmacological treatment

**Renewal — erectile dysfunction due to spinal cord injury**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

Note: Note: Indications marked with \* are Unapproved Indications.

† 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 the above details are correct and that in signing this form I understand I may be audited.**

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

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**Iloprost**

**Initial application — PAH monotherapy**

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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<sup>-5</sup>)

**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**

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 the above details are correct and that in signing this form I understand I may be audited.**

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

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**Iloprost** - continued

**Initial application — PAH dual therapy**

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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<sup>5</sup>)  
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  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 the above details are correct and that in signing this form I understand I may be audited.**

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

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**Iloprost** - continued

**Initial application — PAH triple therapy**

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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<sup>-5</sup>)

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

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 the above details are correct and that in signing this form I understand I may be audited.**

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

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**Iloprost** - *continued*

**Renewal**

Current approval Number (if known):.....

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

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 the above details are correct and that in signing this form I understand I may be audited.**

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**Epoprostenol**

**Initial application — PAH dual therapy**

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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<sup>-5</sup>)

**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**

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 the above details are correct and that in signing this form I understand I may be audited.**

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

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**Epoprostenol - continued**

**Initial application — PAH triple therapy**

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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<sup>-5</sup>)

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

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 the above details are correct and that in signing this form I understand I may be audited.**

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**Epoprostenol** - *continued*

**Renewal**

Current approval Number (if known):.....

Applications only from a respiratory specialist, cardiologist, rheumatologist or any relevant practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

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.

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

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**Dermatologicals**

<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT NHI:</b> .....	<b>REFERRER</b> Reg No: .....
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**Isotretinoin**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice
<b>and</b>	
<input type="checkbox"/>	Applicant has an up to date knowledge of the safety issues around isotretinoin and is competent to prescribe isotretinoin
<b>and</b>	
<input type="checkbox"/>	Patient is of child bearing potential and the possibility of pregnancy has been excluded prior to commencement of treatment and patient has been counselled and understands the risk of teratogenicity if isotretinoin is used during pregnancy and that they must not become pregnant during treatment and for a period of one month after the completion of treatment
<b>or</b>	
<input type="checkbox"/>	Patient is not of child bearing potential

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient is of child bearing potential and the possibility of pregnancy has been excluded prior to commencement of treatment and patient has been counselled and understands the risk of teratogenicity if isotretinoin is used during pregnancy and that they must not become pregnant during treatment and for a period of one month after the completion of treatment
<b>or</b>	
<input type="checkbox"/>	Patient is not of child bearing potential

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

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**Ivermectin**

**Initial application — Scabies**

Applications from any relevant practitioner. Approvals valid for 1 month.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The person has a severe scabies hyperinfestation (Crusted/ Norwegian scabies)
<b>or</b>	
<input type="checkbox"/>	The person has a confirmed diagnosis of scabies or is a close contact of a scabies case
<b>and</b>	
<input type="checkbox"/>	The person is unable to complete topical therapy
<b>or</b>	
<input type="checkbox"/>	Previous treatment with topical therapy has been tried and not cleared the infestation

**Initial application — Other parasitic infections**

Applications from any relevant practitioner. Approvals valid for 1 month.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Filariasis
<b>or</b>	
<input type="checkbox"/>	Cutaneous larva migrans (creeping eruption)
<b>or</b>	
<input type="checkbox"/>	Strongyloidiasis

**Renewal — Scabies**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 1 month.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The person has a severe scabies hyperinfestation (Crusted/ Norwegian scabies)
<b>or</b>	
<input type="checkbox"/>	The person has a confirmed diagnosis of scabies or is a close contact of a scabies case
<b>and</b>	
<input type="checkbox"/>	The person is unable to complete topical therapy
<b>or</b>	
<input type="checkbox"/>	Previous treatment with topical therapy has been tried and not cleared the infestation

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**Ivermectin** - *continued*

**Renewal — Other parasitic infections**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 1 month.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Filariasis <b>or</b> <input type="checkbox"/> Cutaneous larva migrans (creeping eruption) <b>or</b> <input type="checkbox"/> Strongyloidiasis
--

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Tacrolimus Ointment**

**Initial application**

Applications only from a dermatologist, paediatrician or any relevant practitioner on the recommendation of a dermatologist, paediatrician, . Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<p><input type="checkbox"/> Patient has atopic dermatitis on the face</p> <p><b>and</b></p> <p><input type="checkbox"/> Patient has at least one of the following contraindications to topical corticosteroids: periorificial dermatitis, rosacea, documented epidermal atrophy or documented allergy to topical corticosteroids</p>
--

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Acitretin**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice
<b>and</b>	
<input type="checkbox"/>	Applicant has an up to date knowledge of the safety issues around acitretin and is competent to prescribe acitretin
<b>and</b>	
<input type="checkbox"/>	Patient is of child bearing potential and the possibility of pregnancy has been excluded prior to commencement of treatment and patient has been counselled and understands the risk of teratogenicity if acitretin is used during pregnancy and that they must not become pregnant during treatment and for a period of three years after the completion of treatment
<b>or</b>	
<input type="checkbox"/>	Patient is not of child bearing potential

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient is of child bearing potential and the possibility of pregnancy has been excluded prior to commencement of treatment and patient has been counselled and understands the risk of teratogenicity if acitretin is used during pregnancy and that they must not become pregnant during treatment and for a period of three years after the completion of treatment
<b>or</b>	
<input type="checkbox"/>	Patient is not of child bearing potential

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**Pimecrolimus**

**Initial application**

Applications only from a dermatologist, paediatrician, ophthalmologist or any relevant practitioner on the recommendation of a dermatologist, paediatrician or ophthalmologist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<p><b>and</b></p>	<input type="checkbox"/> Patient has atopic dermatitis on the eyelid  <input type="checkbox"/> 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 the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

**Genito-Urinary System**

**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER Reg No:** .....

Reg No: .....      First Names: .....      First Names: .....

Name: .....      Surname: .....      Surname: .....

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Fax Number: .....      Fax Number: .....

**Combined oral contraceptives; Progestogen-only contraceptives (Circle one)**

**Initial application**

Applications from any medical practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

- Patient is on a Social Welfare benefit  
or  
 Patient has an income no greater than the benefit

and  
 Has tried at least one of the fully funded options and has been unable to tolerate it

**Renewal**

Current approval Number (if known):.....

Applications from any medical practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

- Patient is on a Social Welfare benefit  
or  
 Patient has an income no greater than the benefit

Note: The approval numbers of Special Authorities approved after 1 November 1999 are interchangeable between Mercilon and Marvelon. The additional subsidy will fund Mercilon and Marvelon up to the manufacturer's price for each of these products as identified on the Schedule at 1 November 1999.

Special Authorities approved before 1 November 1999 remain valid until the expiry date and can be renewed providing that women are still either:

- on a Social Welfare benefit; or
- have an income no greater than the benefit.

The approval numbers of Special Authorities approved before 1 November 1999 are interchangeable for products within the combined oral contraceptives and progestogen-only contraceptives groups, except Loette and Microgynon 20 ED

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Reg No: .....	First Names: .....	First Names: .....
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**Finasteride**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has symptomatic benign prostatic hyperplasia
<b>and</b>
<input type="checkbox"/> The patient is intolerant of non-selective alpha blockers or these are contraindicated
<b>or</b>
<input type="checkbox"/> Symptoms are not adequately controlled with non-selective alpha blockers

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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Reg No: .....	First Names: .....	First Names: .....
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Fax Number: .....	.....	Fax Number: .....

**Tamsulosin**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has symptomatic benign prostatic hyperplasia
<b>and</b>
<input type="checkbox"/> The patient is intolerant of non-selective alpha blockers or these are contraindicated

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Potassium Citrate**

**Initial application**  
Applications from any relevant practitioner. Approvals valid for 12 months.  
**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has recurrent calcium oxalate urolithiasis
<b>and</b>	
<input type="checkbox"/>	The patient has had more than two renal calculi in the two years prior to the application

**Renewal**  
Current approval Number (if known):.....  
Applications from any relevant practitioner. Approvals valid for 2 years.  
**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefitting from the treatment

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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## **Hormone Preparations - Systemic Excluding Contraceptive Hormones**

**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER** Reg No: .....

Reg No: .....      First Names: .....      First Names: .....

Name: .....      Surname: .....      Surname: .....

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Fax Number: .....      Fax Number: .....

**Cinacalct**

**Initial application — parathyroid carcinoma or calciphylaxis**  
Applications only from a nephrologist or endocrinologist. Approvals valid for 6 months.  
**Prerequisites**(tick boxes where appropriate)

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 arteriopathy)  
**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

**Renewal — parathyroid carcinoma or calciphylaxis**  
Current approval Number (if known):.....  
Applications only from a nephrologist or endocrinologist. Approvals valid without further renewal unless notified.  
**Prerequisites**(tick boxes where appropriate)

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.

**Initial application — primary hyperparathyroidism**  
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.  
**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 the above details are correct and that in signing this form I understand I may be audited.

Signed: ..... Date: .....  
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Fax Number: .....	.....	Fax Number: .....

**Cinacalcet** - *continued*

**Initial application — secondary or tertiary hyperparathyroidism**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has tertiary hyperparathyroidism and markedly elevated parathyroid hormone (PTH) with hypercalcaemia <b>or</b> <input type="checkbox"/> Patient has symptomatic secondary hyperparathyroidism and elevated PTH
<b>and</b>
<input type="checkbox"/> Patient is on renal replacement therapy
<b>and</b>
<input type="checkbox"/> Residual parathyroid tissue has not been localised despite repeat unsuccessful parathyroid explorations <b>or</b> <input type="checkbox"/> Parathyroid tissue is surgically inaccessible <b>or</b> <input type="checkbox"/> Parathyroid surgery is not feasible

**Renewal — secondary or tertiary hyperparathyroidism**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> 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 <b>or</b> <input type="checkbox"/> The patient has not received a kidney transplant and trial of withdrawal of cinacalcet is clinically inappropriate
---

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**Propylthiouracil**

**Initial application**  
Applications from any relevant practitioner. Approvals valid for 2 years.  
**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>		The patient has hyperthyroidism
<b>and</b>		
<input type="checkbox"/>		The patient is intolerant of carbimazole or carbimazole is contraindicated

**Renewal**  
Current approval Number (if known):.....  
Applications from any relevant practitioner. Approvals valid for 2 years.  
**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefitting from the treatment

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

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**SA2032 - Somatropin**

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<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT NHI:</b> .....	<b>REFERRER</b> Reg No: .....
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**Somatropin**

**Initial application — growth hormone deficiency in children**

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months.

**Prerequisites**(tick boxes where appropriate)

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 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

**Renewal — growth hormone deficiency in children**

Current approval Number (if known):.....

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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

**Initial application — Turner syndrome**

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months.

**Prerequisites**(tick boxes where appropriate)

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

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

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**Somatropin - continued**

**Renewal — Turner syndrome**

Current approval Number (if known):.....

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Height velocity is 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)
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	Height velocity is greater than or equal to 2 cm per year, calculated over six months
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	A current bone age is 14 years or under
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	No serious adverse effect that the specialist considers is likely to be attributable to growth hormone treatment has occurred
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	No malignancy has developed since starting growth hormone

**Initial application — short stature without growth hormone deficiency**

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	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
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	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)
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	A current bone age is < 14 years or under (female patients) or < 16 years (male patients)
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	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

**Renewal — short stature without growth hormone deficiency**

Current approval Number (if known):.....

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	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)
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	Height velocity is greater than or equal to 2 cm per year as calculated over six months
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	A current bone age is 14 years or under (female patients) or 16 years or under (male patients)
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	No serious adverse effect that the patient's specialist considers is likely to be attributable to growth hormone treatment has occurred

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

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**Somatropin - continued**

**Initial application — short stature due to chronic renal insufficiency**

Applications only from a paediatric endocrinologist, endocrinologist or renal physician on the recommendation of a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months.

**Prerequisites**(tick boxes where appropriate)

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/1.73m<sup>2</sup> as measured by the Schwartz method (Height(cm)/plasma creatinine (umol/l)) × 40 = corrected GFR (ml/min/1.73m<sup>2</sup>) in a child who may or may not be receiving dialysis

**or**

The patient has received a renal transplant and has received < 5mg/ m<sup>2</sup>/day of prednisone or equivalent for at least 6 months.

**Renewal — short stature due to chronic renal insufficiency**

Current approval Number (if known):.....

Applications only from a paediatric endocrinologist, endocrinologist or renal physician on the recommendation of a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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 the above details are correct and that in signing this form I understand I may be audited.**

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

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**Somatropin - continued**

**Initial application — Prader-Willi syndrome**

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has a diagnosis of Prader-Willi syndrome that has been confirmed by genetic testing or clinical scoring criteria
<b>and</b>	
<input type="checkbox"/>	The patient is aged six months or older
<b>and</b>	
<input type="checkbox"/>	A current bone age is < 14 years (female patients) or < 16 years (male patients)
<b>and</b>	
<input type="checkbox"/>	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
<b>and</b>	
<input type="checkbox"/>	The patient is aged two years or older
<b>and</b>	
<input type="checkbox"/>	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
<b>or</b>	
<input type="checkbox"/>	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

**Renewal — Prader-Willi syndrome**

Current approval Number (if known):.....

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	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)
<b>and</b>	
<input type="checkbox"/>	Height velocity is greater than or equal to 2 cm per year as calculated over six months
<b>and</b>	
<input type="checkbox"/>	A current bone age is 14 years or under (female patients) or 16 years or under (male patients)
<b>and</b>	
<input type="checkbox"/>	No serious adverse effect that the patient's specialist considers is likely to be attributable to growth hormone treatment has occurred
<b>and</b>	
<input type="checkbox"/>	No malignancy has developed after growth hormone therapy was commenced
<b>and</b>	
<input type="checkbox"/>	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

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**Somatropin** - *continued*

**Initial application — adults and adolescents**

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months.

**Prerequisites**(tick boxes where appropriate)

- 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 the serum IGF-I is within 1 standard deviation of the mean normal value for age and sex; and 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.

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**Somatropin - continued**

**Renewal — adults and adolescents**

Current approval Number (if known):.....

Applications only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has been treated with somatropin for < 12 months
- and**
- There has been an improvement in Quality of Life 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 been increased within ±1SD of the mean of the normal range for age and sex
- 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 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

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 the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

**APPLICATION FOR  
WAIVER OF RULE  
BY SPECIAL AUTHORITY**

<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT</b> NHI: .....	<b>REFERRER</b> Reg No: .....
Reg No: .....	First Names: .....	First Names: .....
Name: .....	Surname: .....	Surname: .....
Address: .....	DOB: .....	Address: .....
.....	Address: .....	.....
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Fax Number: .....	.....	Fax Number: .....

**Cabergoline**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Hyperprolactinemia <b>or</b> <input type="checkbox"/> Acromegaly* <b>or</b> <input type="checkbox"/> Inhibition of lactation
---

**Renewal — for patients who have previously been funded under Special Authority form SA1031**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

<input type="checkbox"/> The patient has previously held a valid Special Authority which has expired and the treatment remains appropriate and the patient is benefiting from treatment
---

Note: Indication marked with \* is an unapproved indication.

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

## Infections - Agents for Systemic Use

<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT NHI:</b> .....	<b>REFERRER</b> Reg No: .....
Reg No: .....	First Names: .....	First Names: .....
Name: .....	Surname: .....	Surname: .....
Address: .....	DOB: .....	Address: .....
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Fax Number: .....	.....	Fax Number: .....

**Albendazole**

**Initial application**

Applications only from an infectious disease specialist or clinical microbiologist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

The patient has hydatids

**Renewal**

Current approval Number (if known):.....

Applications only from an infectious disease specialist or clinical microbiologist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefitting from the treatment

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER** Reg No: .....

Reg No: .....      First Names: .....      First Names: .....

Name: .....      Surname: .....      Surname: .....

Address: .....      DOB: .....      Address: .....

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Fax Number: .....      Fax Number: .....

### Azithromycin

#### Initial application — bronchiolitis obliterans syndrome, cystic fibrosis and atypical Mycobacterium infections

Applications only from a relevant specialist. Approvals valid without further renewal unless notified.

**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.

#### Initial application — non-cystic fibrosis bronchiectasis\*

Applications only from a respiratory specialist or paediatrician. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- 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.

#### Renewal — non-cystic fibrosis bronchiectasis\*

Current approval Number (if known):.....

Applications only from a respiratory specialist or paediatrician. Approvals valid for 12 months.

The patient must not have had more than 1 prior approval.

**Prerequisites**(tick boxes where appropriate)

- 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: No further renewals will be subsidised. A maximum of 24 months of azithromycin treatment for non-cystic fibrosis bronchiectasis will be subsidised. Indications marked with \* are unapproved indications

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**APPLICANT** (stamp or sticker acceptable)      **PATIENT** NHI: .....      **REFERRER** Reg No: .....

Reg No: .....      First Names: .....      First Names: .....

Name: .....      Surname: .....      Surname: .....

Address: .....      DOB: .....      Address: .....

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Fax Number: .....      Fax Number: .....

### Clarithromycin

#### Initial application — Mycobacterial infections

Applications only from a respiratory specialist, infectious disease specialist or paediatrician. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

- Atypical mycobacterial infection
- or
- Mycobacterium tuberculosis infection where there is drug-resistance or intolerance to standard pharmaceutical agents

#### Initial application — Helicobacter pylori eradication

Applications from any relevant practitioner. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

- For the eradication of helicobacter pylori in a patient unable to swallow tablets
- and
- For use only in combination with omeprazole and amoxicillin as part of a triple therapy regimen

#### Initial application — Prophylaxis of infective endocarditis

Applications from any relevant practitioner. Approvals valid for 3 months.

**Prerequisites**(tick box where appropriate)

- Prophylaxis of infective endocarditis associated with surgical or dental procedures if amoxicillin is contra-indicated

#### Renewal — Mycobacterial infections

Current approval Number (if known):.....

Applications only from a respiratory specialist, infectious disease specialist or paediatrician. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

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

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)



**APPLICATION FOR  
MANUFACTURERS PRICE  
BY SPECIAL AUTHORITY**

<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT</b> NHI: .....	<b>REFERRER</b> Reg No: .....
Reg No: .....	First Names: .....	First Names: .....
Name: .....	Surname: .....	Surname: .....
Address: .....	DOB: .....	Address: .....
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Fax Number: .....	.....	Fax Number: .....

**Minocycline hydrochloride Tab 50 mg**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The patient has rosacea

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT NHI:</b> .....	<b>REFERRER</b> Reg No: .....
Reg No: .....	First Names: .....	First Names: .....
Name: .....	Surname: .....	Surname: .....
Address: .....	DOB: .....	Address: .....
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Fax Number: .....	.....	Fax Number: .....

**Tetracycline**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

- |  |
|--|
| <input type="checkbox"/> For the eradication of helicobacter pylori following unsuccessful treatment with appropriate first-line therapy<br><b>and</b><br><input type="checkbox"/> For use only in combination with bismuth as part of a quadruple therapy regimen |
|--|

I confirm the above details are correct and that in signing this form I understand I may be audited.

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Fax Number: .....      Fax Number: .....

**Moxifloxacin**

**Initial application — Tuberculosis**

Applications only from a respiratory specialist or infectious disease specialist. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

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

Note: Indications marked with \* are unapproved indications.

**Renewal**

Current approval Number (if known):.....

Applications only from a respiratory specialist or infectious disease specialist. Approvals valid for 1 year.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

**Initial application — Mycoplasma genitalium**

Applications only from a sexual health specialist or Practitioner on the recommendation of a sexual health specialist. Approvals valid for 1 month.

**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 the above details are correct and that in signing this form I understand I may be audited.

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

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Fax Number: .....	.....	Fax Number: .....

**Moxifloxacin** - *continued*

**Initial application — Penetrating eye injury**

Applications only from an ophthalmologist. Approvals valid for 1 month.

**Prerequisites**(tick box where appropriate)

The patient requires prophylaxis following a penetrating eye injury and treatment is for 5 days only

Note: Indications marked with \* are unapproved indications.

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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Reg No: .....	First Names: .....	First Names: .....
Name: .....	Surname: .....	Surname: .....
Address: .....	DOB: .....	Address: .....
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Fax Number: .....	.....	Fax Number: .....

**Pyrimethamine**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> For the treatment of toxoplasmosis in patients with HIV for a period of 3 months
<b>or</b>
<input type="checkbox"/> For pregnant patients for the term of the pregnancy
<b>or</b>
<input type="checkbox"/> For infants with congenital toxoplasmosis until 12 months of age

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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Reg No: .....	First Names: .....	First Names: .....
Name: .....	Surname: .....	Surname: .....
Address: .....	DOB: .....	Address: .....
.....	Address: .....	.....
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Fax Number: .....	.....	Fax Number: .....

**Sulfadiazine**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<b>or</b>	<input type="checkbox"/> For the treatment of toxoplasmosis in patients with HIV for a period of 3 months
<b>or</b>	<input type="checkbox"/> For pregnant patients for the term of the pregnancy
<b>or</b>	<input type="checkbox"/> For infants with congenital toxoplasmosis until 12 months of age

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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Reg No: .....	First Names: .....	First Names: .....
Name: .....	Surname: .....	Surname: .....
Address: .....	DOB: .....	Address: .....
.....	Address: .....	.....
.....	.....	.....
Fax Number: .....	.....	Fax Number: .....

**Paromomycin**

**Initial application**

Applications only from an infectious disease specialist, clinical microbiologist or gastroenterologist. Approvals valid for 1 month.

**Prerequisites**(tick boxes where appropriate)

<b>or</b>	<input type="checkbox"/> Patient has confirmed cryptosporidium infection
	<input type="checkbox"/> For the eradication of Entamoeba histolytica carriage

**Renewal**

Current approval Number (if known):.....

Applications only from an infectious disease specialist, clinical microbiologist or gastroenterologist. Approvals valid for 1 month.

**Prerequisites**(tick boxes where appropriate)

<b>or</b>	<input type="checkbox"/> Patient has confirmed cryptosporidium infection
	<input type="checkbox"/> For the eradication of Entamoeba histolytica carriage

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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Reg No: .....	First Names: .....	First Names: .....
Name: .....	Surname: .....	Surname: .....
Address: .....	DOB: .....	Address: .....
.....	Address: .....	.....
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Fax Number: .....	.....	Fax Number: .....

**Fluconazole oral liquid**

**Initial application — Systemic candidiasis**

Applications from any relevant practitioner. Approvals valid for 6 weeks.

**Prerequisites**(tick boxes where appropriate)

- Patient requires prophylaxis for, or treatment of systemic candidiasis
- and
- Patient is unable to swallow capsules

**Initial application — Immunocompromised**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- Patient is immunocompromised
- and
- Patient is at moderate to high risk of invasive fungal infection
- and
- Patient is unable to swallow capsules

**Renewal — Systemic candidiasis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 weeks.

**Prerequisites**(tick boxes where appropriate)

- Patient requires prophylaxis for, or treatment of systemic candidiasis
- and
- Patient is unable to swallow capsules

**Renewal — Immunocompromised**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- Patient remains immunocompromised
- and
- Patient remains at moderate to high risk of invasive fungal infection
- and
- Patient is unable to swallow capsules

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT NHI:</b> .....	<b>REFERRER</b> Reg No: .....
Reg No: .....	First Names: .....	First Names: .....
Name: .....	Surname: .....	Surname: .....
Address: .....	DOB: .....	Address: .....
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Fax Number: .....	.....	Fax Number: .....

**Itraconazole**

**Initial application**

Applications only from an infectious disease specialist, clinical microbiologist, clinical immunologist or any relevant practitioner on the recommendation of a infectious disease physician, clinical microbiologist or clinical immunologist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

The patient has a congenital immune deficiency

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefitting from the treatment

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

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<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT NHI:</b> .....	<b>REFERRER</b> Reg No: .....
Reg No: .....	First Names: .....	First Names: .....
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Address: .....	DOB: .....	Address: .....
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Fax Number: .....	.....	Fax Number: .....

**Voriconazole**

**Initial application — invasive fungal infection**

Applications only from a haematologist, infectious disease specialist or clinical microbiologist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient is immunocompromised
<b>and</b>	
<input type="checkbox"/>	Applicant is part of a multidisciplinary team including an infectious disease specialist
<b>and</b>	
<input type="checkbox"/>	Patient has proven or probable invasive aspergillus infection
<b>or</b>	
<input type="checkbox"/>	Patient has possible invasive aspergillus infection
<b>or</b>	
<input type="checkbox"/>	Patient has fluconazole resistant candidiasis
<b>or</b>	
<input type="checkbox"/>	Patient has mould strain such as <i>Fusarium</i> spp. and <i>Scedosporium</i> spp

**Renewal — invasive fungal infection**

Current approval Number (if known):.....

Applications only from a haematologist, infectious disease specialist or clinical microbiologist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient is immunocompromised
<b>and</b>	
<input type="checkbox"/>	Applicant is part of a multidisciplinary team including an infectious disease specialist
<b>and</b>	
<input type="checkbox"/>	Patient continues to require treatment for proven or probable invasive aspergillus infection
<b>or</b>	
<input type="checkbox"/>	Patient continues to require treatment for possible invasive aspergillus infection
<b>or</b>	
<input type="checkbox"/>	Patient has fluconazole resistant candidiasis
<b>or</b>	
<input type="checkbox"/>	Patient has mould strain such as <i>Fusarium</i> spp. and <i>Scedosporium</i> spp

**Initial application — Invasive fungal infection prophylaxis**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient is at risk of invasive fungal infection
<b>and</b>	
<input type="checkbox"/>	Voriconazole is prescribed by, or recommended by a haematologist, transplant physician, infectious disease specialist, paediatric haematologist or paediatric oncologist
<b>or</b>	
<input type="checkbox"/>	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 the above details are correct and that in signing this form I understand I may be audited.**

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

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**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER** Reg No: .....

Reg No: .....      First Names: .....      First Names: .....

Name: .....      Surname: .....      Surname: .....

Address: .....      DOB: .....      Address: .....

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Fax Number: .....      Fax Number: .....

**Voriconazole** - *continued*

**Renewal — Invasive fungal infection prophylaxis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The patient is at risk of invasive fungal infection
<b>and</b>
<input type="checkbox"/> Voriconazole is prescribed by, or recommended by a haematologist, transplant physician, infectious disease specialist, paediatric haematologist or paediatric oncologist
<b>or</b>
<input type="checkbox"/> 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 the above details are correct and that in signing this form I understand I may be audited.

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

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Reg No: .....      First Names: .....      First Names: .....

Name: .....      Surname: .....      Surname: .....

Address: .....      DOB: .....      Address: .....

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**Posaconazole**

**Initial application**

Applications only from a haematologist or infectious disease specialist. Approvals valid for 6 weeks.

**Prerequisites**(tick boxes where appropriate)

- Patient has acute myeloid leukaemia and is to be treated with high dose remission induction, re-induction or consolidation chemotherapy
- or
- Patient has received a stem cell transplant and has graft versus host disease and is on significant immunosuppressive therapy\*

**Renewal**

Current approval Number (if known):.....

Applications only from a haematologist or infectious disease specialist. Approvals valid for 6 weeks.

**Prerequisites**(tick boxes where appropriate)

- Patient has acute myeloid leukaemia and is to be treated with high dose remission induction, re-induction or consolidation therapy
- or
- Patient has received a stem cell transplant and has graft versus host disease and is on significant immunosuppression\* and requires on going posaconazole treatment

Note: \* Graft versus host disease (GVHD) on significant immunosuppression is defined as acute GVHD, grade II to IV, or extensive chronic GVHD, or if they were being treated with intensive immunosuppressive therapy consisting of either high-dose corticosteroids (1 mg or greater per kilogram of body weight per day for patients with acute GVHD or 0.8 mg or greater per kilogram every other day for patients with chronic GVHD), antithymocyte globulin, or a combination of two or more immunosuppressive agents or types of treatment.

**Initial application — Invasive fungal infection prophylaxis**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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 the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Posaconazole** - continued

**Renewal — Invasive fungal infection prophylaxis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient is at risk of invasive fungal infection
<b>and</b>	
<input type="checkbox"/>	Posaconazole is prescribed by, or recommended by a haematologist, transplant physician, infectious disease specialist, paediatric haematologist or paediatric oncologist
<b>or</b>	
<input type="checkbox"/>	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 the above details are correct and that in signing this form I understand I may be audited.

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**Primaquine**

**Initial application**  
Applications only from an infectious disease specialist or clinical microbiologist. Approvals valid for 1 month.  
**Prerequisites**(tick boxes where appropriate)

The patient has vivax or ovale malaria  
**and**  
 Primaquine is to be given for a maximum of 21 days

**Renewal**  
Current approval Number (if known):.....  
Applications only from an infectious disease specialist or clinical microbiologist. Approvals valid for 1 month.  
**Prerequisites**(tick boxes where appropriate)

The patient has relapsed vivax or ovale malaria  
**and**  
 Primaquine is to be given for a maximum of 21 days

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Linezolid**

**Initial application — multi-drug resistant tuberculosis**

Applications from any relevant practitioner. Approvals valid for 18 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The person has multi-drug resistant tuberculosis (MDR-TB)
<b>and</b>	
<input type="checkbox"/>	Ministry of Health's Tuberculosis Clinical Network has reviewed the individual case and recommends linezolid as part of the treatment regimen

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Bedaquiline**

**Initial application — multi-drug resistant tuberculosis**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The person has multi-drug resistant tuberculosis (MDR-TB)
<b>and</b>	
<input type="checkbox"/>	Ministry of Health's Tuberculosis Clinical Network has reviewed the individual case and recommends bedaquiline as part of the treatment regimen

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Lamivudine**

**Initial application**

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 1 year.

**Prerequisites**(tick box where appropriate)

Used for the treatment or prevention of hepatitis B

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

Used for the treatment or prevention of hepatitis B

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**Valganciclovir**

**Initial application — transplant cytomegalovirus prophylaxis**

Applications only from a relevant specialist. Approvals valid for 3 months.

**Prerequisites**(tick box where appropriate)

The patient has undergone a solid organ transplant and requires valganciclovir for CMV prophylaxis

**Renewal — transplant cytomegalovirus prophylaxis**

Current approval Number (if known):.....

Applications only from a relevant specialist. Approvals valid for 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

**Initial application — cytomegalovirus prophylaxis following anti-thymocyte globulin**

Applications only from a relevant specialist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

Patient has undergone a solid organ transplant and received valganciclovir under Special Authority more than 2 years ago (27 months)

**and**

Patient has received anti-thymocyte globulin and requires valganciclovir for CMV prophylaxis

**Renewal — cytomegalovirus prophylaxis following anti-thymocyte globulin**

Current approval Number (if known):.....

Applications only from a relevant specialist. Approvals valid for 3 months.

**Prerequisites**(tick box where appropriate)

The patient has received a further course of anti-thymocyte globulin and requires valganciclovir for CMV prophylaxis

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**Valganciclovir - continued**

**Initial application — Lung transplant cytomegalovirus prophylaxis**

Applications only from a relevant specialist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has undergone a lung transplant
<b>and</b>
<input type="checkbox"/> The donor was cytomegalovirus positive and the patient is cytomegalovirus negative
<b>or</b>
<input type="checkbox"/> The recipient is cytomegalovirus positive
<b>and</b>
<input type="checkbox"/> Patient has a high risk of CMV disease

**Initial application — Cytomegalovirus in immunocompromised patients**

Applications only from a relevant specialist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient is immunocompromised
<b>and</b>
<input type="checkbox"/> Patient has cytomegalovirus syndrome or tissue invasive disease
<b>or</b>
<input type="checkbox"/> Patient has rapidly rising plasma CMV DNA in absence of disease
<b>or</b>
<input type="checkbox"/> Patient has cytomegalovirus retinitis

**Renewal — Cytomegalovirus in immunocompromised patients**

Current approval Number (if known):.....

Applications only from a relevant specialist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient is immunocompromised
<b>and</b>
<input type="checkbox"/> Patient has cytomegalovirus syndrome or tissue invasive disease
<b>or</b>
<input type="checkbox"/> Patient has rapidly rising plasma CMV DNA in absence of disease
<b>or</b>
<input type="checkbox"/> Patient has cytomegalovirus retinitis

Note: for the purpose of this Special Authority "immunocompromised" includes transplant recipients, patients with immunosuppressive diseases (e.g. HIV) or those receiving immunosuppressive treatment for other conditions.

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**Emtricitabine with tenofovir disoproxil**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 24 months.

**Prerequisites**(tick boxes where appropriate)

<b>and</b>	<input type="checkbox"/> Patient has tested HIV negative, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion
	<input type="checkbox"/> 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/PrEP/>

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 24 months.

**Prerequisites**(tick boxes where appropriate)

<b>and</b>	<input type="checkbox"/> Patient has tested HIV negative, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion
	<input type="checkbox"/> 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/PrEP/>

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**Antiretrovirals**

**Initial application — Confirmed HIV**

Applications only from a named specialist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The patient has confirmed HIV infection

Note: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals.

Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

**Renewal — Confirmed HIV**

Current approval Number (if known):.....

Applications only from a named specialist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

**Initial application — Prevention of maternal transmission**

Applications only from a named specialist. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Prevention of maternal foetal transmission <b>or</b> <input type="checkbox"/> Treatment of the newborn for up to eight weeks
---

Note: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals.

Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

Some antiretrovirals are unapproved or contraindicated for this indication. Practitioners prescribing these medications should exercise their own skill, judgement, expertise and discretion, and make their own prescribing decisions with respect to the use of a Pharmaceutical for an indication for which it is not approved or contraindicated.

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

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**Antiretrovirals - continued**

**Initial application — post-exposure prophylaxis following exposure to HIV**

Applications from any relevant practitioner. Approvals valid for 4 weeks.

**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: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals. Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals. Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines for PEP (<https://www.ashm.org.au>)

**Renewal — second or subsequent post-exposure prophylaxis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 4 weeks.

**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

**Initial application — Percutaneous exposure**

Applications only from a named specialist. Approvals valid for 6 weeks.

**Prerequisites**(tick box where appropriate)

The patient has percutaneous exposure to blood known to be HIV positive

Note: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals. Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

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

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**Antiretrovirals** - *continued*

**Renewal — Second or subsequent percutaneous exposure**

Current approval Number (if known):.....

Applications only from a named specialist. Approvals valid for 6 weeks.

**Prerequisites**(tick box where appropriate)

The patient has percutaneous exposure to blood known to be HIV positive

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**Pegylated Interferon alfa-2A**

**Initial application — chronic hepatitis C - genotype 1, 4, 5 or 6 infection or co-infection with HIV or genotype 2 or 3 post liver transplant**

Applications from any specialist. Approvals valid for 18 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has chronic hepatitis C, genotype 1, 4, 5 or 6 infection <b>or</b> <input type="checkbox"/> Patient has chronic hepatitis C and is co-infected with HIV <b>or</b> <input type="checkbox"/> Patient has chronic hepatitis C genotype 2 or 3 and has received a liver transplant <b>and</b> <input type="checkbox"/> Maximum of 48 weeks therapy
---

**Renewal — Chronic hepatitis C - genotype 1 infection**

Current approval Number (if known):.....

Applications only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 18 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has chronic hepatitis C, genotype 1 <b>and</b> <input type="checkbox"/> Patient has had previous treatment with pegylated interferon and ribavirin <b>and</b> <input type="checkbox"/> Patient has responder relapsed <b>or</b> <input type="checkbox"/> Patient was a partial responder <b>and</b> <input type="checkbox"/> Patient is to be treated in combination with boceprevir <b>and</b> <input type="checkbox"/> Maximum of 48 weeks therapy
---

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**Pegylated Interferon alfa-2A** - *continued*

**Initial application — Chronic Hepatitis C - genotype 1 infection treatment more than 4 years prior**

Applications only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 18 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has chronic hepatitis C, genotype 1
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	Patient has had previous treatment with pegylated interferon and ribavirin
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	Patient has responder relapsed
<b>or</b>	<input type="checkbox"/>
<input type="checkbox"/>	Patient was a partial responder
<b>or</b>	<input type="checkbox"/>
<input type="checkbox"/>	Patient received interferon treatment prior to 2004
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	Patient is to be treated in combination with boceprevir
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	Maximum of 48 weeks therapy

**Initial application — chronic hepatitis C - genotype 2 or 3 infection without co-infection with HIV**

Applications from any specialist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has chronic hepatitis C, genotype 2 or 3 infection
<b>and</b>	<input type="checkbox"/>
<input type="checkbox"/>	Maximum of 6 months therapy

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**Pegylated Interferon alfa-2A** - *continued*

**Initial application — Hepatitis B**

Applications only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 18 months.

**Prerequisites**(tick boxes where appropriate)

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 log<sub>10</sub> IU/ml

**and**

HBeAg positive

**or**

Serum HBV DNA greater than or equal to 2,000 units/ml and significant fibrosis (Metavir Stage F2 or greater 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

**and**  Maximum of 48 weeks therapy

**Initial application — myeloproliferative disorder or cutaneous T cell lymphoma**

Applications from any relevant practitioner. Approvals valid for 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 the above details are correct and that in signing this form I understand I may be audited.**

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**Pegylated Interferon alfa-2A - continued**

**Renewal — myeloproliferative disorder or cutaneous T cell lymphoma**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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.

**Initial application — post-allogenic bone marrow transplant**

Applications from any relevant practitioner. Approvals valid for 3 months.

**Prerequisites**(tick box where appropriate)

Patient has received an allogenic bone marrow transplant\* and has evidence of disease relapse

**Renewal — post-allogenic bone marrow transplant**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 3 months.

**Prerequisites**(tick box where appropriate)

Patient is responding and ongoing treatment remains appropriate

Note: Indications marked with \* are unapproved indications.

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Fax Number: .....	.....	Fax Number: .....

**Fosfomycin**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 2 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has an acute, symptomatic, bacteriologically-proven uncomplicated urinary tract infection (UTI)/cystitis with Escherichia Coli
<b>and</b>	
<input type="checkbox"/>	Microbiological testing confirms the pathogen is resistant to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin
<b>or</b>	
<input type="checkbox"/>	The patient has a contraindication or intolerance to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin that the pathogen is susceptible to

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has an acute, symptomatic, bacteriologically-proven uncomplicated urinary tract infection (UTI)/cystitis with Escherichia Coli
<b>and</b>	
<input type="checkbox"/>	Microbiological testing confirms the pathogen is resistant to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin
<b>or</b>	
<input type="checkbox"/>	The patient has a contraindication or intolerance to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin that the pathogen is susceptible to

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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## Musculoskeletal System

<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT</b> NHI: .....	<b>REFERRER</b> Reg No: .....
Reg No: .....	First Names: .....	First Names: .....
Name: .....	Surname: .....	Surname: .....
Address: .....	DOB: .....	Address: .....
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Fax Number: .....	.....	Fax Number: .....

**Capsaicin**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The patient has osteoarthritis that is not responsive to paracetamol and oral non-steroidal anti-inflammatories are contraindicated

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER** Reg No: .....

Reg No: .....      First Names: .....      First Names: .....

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**Raloxifene**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**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 less 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.

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**Teriparatide**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 18 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has severe, established osteoporosis
<b>and</b>	
<input type="checkbox"/>	The patient has a documented T-score less than or equal to -3.0 (see Notes)
<b>and</b>	
<input type="checkbox"/>	The patient has had two or more fractures due to minimal trauma
<b>and</b>	
<input type="checkbox"/>	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 Special Authority 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.
- d) A maximum of 18 months of treatment (18 cartridges) will be subsidised.

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**Denosumab**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

The patient has severe, established osteoporosis

**and**

The patient is female and postmenopausal

**or**

The patient is male or non-binary

**and**

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 Note)

**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

**or**

History of two significant osteoporotic fractures demonstrated radiologically

**or**

Documented T-Score less than or equal to -3.0 (see Note)

**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 Note)

**or**

Patient has had a Special Authority approval for alendronate (Underlying cause - Osteoporosis) prior to 1 February 2019 or has had a Special Authority approval for raloxifene

**and**

Zoledronic acid is contraindicated because the patient's creatinine clearance is less than 35 mL/min

**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)

**and**

The patient must not receive concomitant treatment with any other funded antiresorptive agent for this condition or teriparatide

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 treatment with denosumab
- 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
- e) Antiresorptive agents and their adequate doses for the purposes of this Special Authority are defined as: risedronate sodium tab 35 mg once weekly; alendronate sodium tab 70 mg or tab 70 mg with cholecalciferol 5,600 iu once weekly; raloxifene hydrochloride tab 60 mg once daily. 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

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**Benzbromarone**

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The treatment remains appropriate and the patient is benefitting from the treatment
<b>and</b>	
<input type="checkbox"/>	There is no evidence of liver toxicity and patient is continuing to receive regular (at least every three months) liver function tests

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**Febuxostat**

**Initial application — Gout**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has been diagnosed with gout
<b>and</b>
<input type="checkbox"/> 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
<b>or</b>
<input type="checkbox"/> 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
<b>or</b>
<input type="checkbox"/> 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)
<b>or</b>
<input type="checkbox"/> The patient has previously had an initial Special Authority approval for benzbromarone for treatment of gout.

**Initial application — Tumour lysis syndrome**

Applications only from a haematologist or oncologist. Approvals valid for 6 weeks.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient is scheduled to receive cancer therapy carrying an intermediate or high risk of tumour lysis syndrome
<b>and</b>
<input type="checkbox"/> Patient has a documented history of allopurinol intolerance

**Renewal — Gout**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefitting from treatment

**Renewal — Tumour lysis syndrome**

Current approval Number (if known):.....

Applications only from a haematologist or oncologist. Approvals valid for 6 weeks.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefitting from treatment

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## **Nervous System**

<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT NHI:</b> .....	<b>REFERRER</b> Reg No: .....
Reg No: .....	First Names: .....	First Names: .....
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**Riluzole**

**Initial application**

Applications only from a neurologist or respiratory specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has amyotrophic lateral sclerosis with disease duration of 5 years or less
<b>and</b>	
<input type="checkbox"/>	The patient has at least 60 percent of predicted forced vital capacity within 2 months prior to the initial application
<b>and</b>	
<input type="checkbox"/>	The patient has not undergone a tracheostomy
<b>and</b>	
<input type="checkbox"/>	The patient has not experienced respiratory failure
<b>and</b>	
<input type="checkbox"/>	The patient is ambulatory
<b>or</b>	
<input type="checkbox"/>	The patient is able to use upper limbs
<b>or</b>	
<input type="checkbox"/>	The patient is able to swallow

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 18 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has not undergone a tracheostomy
<b>and</b>	
<input type="checkbox"/>	The patient has not experienced respiratory failure
<b>and</b>	
<input type="checkbox"/>	The patient is ambulatory
<b>or</b>	
<input type="checkbox"/>	The patient is able to use upper limbs
<b>or</b>	
<input type="checkbox"/>	The patient is able to swallow

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**Topical local anaesthetics (EMLA; LMX4)**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

The patient is a child with a chronic medical condition requiring frequent injections or venepuncture

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

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Reg No: .....      First Names: .....      First Names: .....

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Address: .....      DOB: .....      Address: .....

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**Vigabatrin**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 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.

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**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 the above details are correct and that in signing this form I understand I may be audited.

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**Lacosamide**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 15 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has focal epilepsy <b>and</b> <input type="checkbox"/> 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.

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 24 months.

**Prerequisites**(tick box where appropriate)

<input type="checkbox"/> The 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
--

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**Stiripentol**

**Initial application**

Applications only from a paediatric neurologist or Practitioner on the recommendation of a paediatric neurologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has confirmed diagnosis of Dravet syndrome <b>and</b> <input type="checkbox"/> 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.

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The patient continues to benefit from treatment as measured by reduced seizure frequency from baseline

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**Hyoscine (Scopolamine)**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	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	
<input type="checkbox"/>	Control of clozapine-induced hypersalivation where trials of at least two other alternative treatments have proven ineffective

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 1 year.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

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**Aprepitant**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

The patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

The patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy

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**Risperidone**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<b>or</b>	<input type="checkbox"/> The patient has had an initial Special Authority approval for paliperidone depot injection or olanzapine depot injection or aripiprazole depot injection			
	<table border="1"> <tr> <td rowspan="3" style="vertical-align: middle;"><b>and</b></td> <td><input type="checkbox"/> The patient has schizophrenia or other psychotic disorder</td> </tr> <tr> <td><input type="checkbox"/> Has not been able to adhere with treatment using oral atypical antipsychotic agents</td> </tr> <tr> <td><input type="checkbox"/> 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</td> </tr> </table>	<b>and</b>	<input type="checkbox"/> The patient has schizophrenia or other psychotic disorder	<input type="checkbox"/> Has not been able to adhere with treatment using oral atypical antipsychotic agents
<b>and</b>	<input type="checkbox"/> The patient has schizophrenia or other psychotic disorder			
	<input type="checkbox"/> Has not been able to adhere with treatment using oral atypical antipsychotic agents			
	<input type="checkbox"/> 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			

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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 the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Olanzapine depot injection**

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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 the above details are correct and that in signing this form I understand I may be audited.

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**Aripiprazole**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The patient has had an initial Special Authority approval for risperidone depot injection, paliperidone depot injection or olanzapine depot injection <b>or</b> <input type="checkbox"/> The patient has schizophrenia or other psychotic disorder <b>and</b> <input type="checkbox"/> The patient has received treatment with oral atypical antipsychotic agents but has been unable to adhere <b>and</b> <input type="checkbox"/> 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 <b>or</b> <input type="checkbox"/> Patient has been unable to access olanzapine depot injection due to supply issues with olanzapine depot injection, or otherwise would have been started on olanzapine depot injection but has been unable to due to supply issues with olanzapine depot injection
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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 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.

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**Paliperidone depot injection**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<b>or</b>	<input type="checkbox"/> The patient has had an initial Special Authority approval for risperidone depot injection or olanzapine depot injection or aripiprazole depot injection			
	<table border="1"> <tr> <td rowspan="3" style="vertical-align: middle;"><b>and</b></td> <td><input type="checkbox"/> The patient has schizophrenia or other psychotic disorder</td> </tr> <tr> <td><input type="checkbox"/> Has been unable to adhere to treatment using oral atypical antipsychotic agents</td> </tr> <tr> <td><input type="checkbox"/> 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</td> </tr> </table>	<b>and</b>	<input type="checkbox"/> The patient has schizophrenia or other psychotic disorder	<input type="checkbox"/> Has been unable to adhere to treatment using oral atypical antipsychotic agents
<b>and</b>	<input type="checkbox"/> The patient has schizophrenia or other psychotic disorder			
	<input type="checkbox"/> Has been unable to adhere to treatment using oral atypical antipsychotic agents			
	<input type="checkbox"/> 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			

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

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**Paliperidone palmitate**

**Initial application**  
Applications from any relevant practitioner. Approvals valid for 12 months.  
**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>		The patient has schizophrenia
<b>and</b>		
<input type="checkbox"/>		The patient has had an initial Special Authority approval for paliperidone once-monthly depot injection

**Renewal**  
Current approval Number (if known):.....  
Applications from any relevant practitioner. Approvals valid for 12 months.  
**Prerequisites**(tick box where appropriate)

<input type="checkbox"/>	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
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**Multiple Sclerosis**

**Initial application — Multiple Sclerosis - dimethyl fumarate, fingolimod, glatiramer acetate, interferon beta-1-alpha, interferon beta-1-beta, natalizumab and teriflunomide**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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 the above details are correct and that in signing this form I understand I may be audited.**

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

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**Multiple Sclerosis** - *continued*

**Renewal — Multiple Sclerosis - dimethyl fumarate, fingolimod, glatiramer acetate, interferon beta-1-alpha, interferon beta-1-beta, natalizumab and teriflunomide**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

Patient has had an EDSS score of 0 to 6.0 (inclusive) with or without the use of 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.

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**Ocrelizumab**

**Initial application — Multiple Sclerosis - ocrelizumab**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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.

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**Ocrelizumab** - *continued*

**Renewal — Multiple Sclerosis - ocrelizumab**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

- Patient has had an EDSS score of 0 to 6.0 (inclusive) with or without the use of 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.

**Initial application — Primary Progressive Multiple Sclerosis**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Renewal — Primary Progressive Multiple Sclerosis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

- 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 the above details are correct and that in signing this form I understand I may be audited.**

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**Phenobarbitone**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> For the treatment of terminal agitation that is unresponsive to other agents <b>and</b> <input type="checkbox"/> The applicant is part of a multidisciplinary team working in palliative care
--

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**Melatonin**

**Initial application**

Applications only from a psychiatrist, paediatrician, neurologist, respiratory specialist or medical practitioner on the recommendation of a psychiatrist, paediatrician, neurologist or respiratory specialist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- 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 and were unsuccessful, 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\*

**Renewal**

Current approval Number (if known):.....

Applications only from a psychiatrist, paediatrician, neurologist, respiratory specialist or medical practitioner on the recommendation of a psychiatrist, paediatrician, neurologist or respiratory specialist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- 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

Note: Indications marked with \* are unapproved indications.

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**Nusinersen**

**Initial application — spinal muscular atrophy (SMA)**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has genetic documentation of homozygous SMN1 gene deletion, homozygous SMN1 point mutation, or compound heterozygous mutation
<b>and</b>	
<input type="checkbox"/>	Patient is 18 years of age or under
<b>and</b>	
<input type="checkbox"/>	Patient has experienced the defined signs and symptoms of SMA type I, II or IIIa prior to three years of age
<b>or</b>	
<input type="checkbox"/>	Patient is pre-symptomatic
<b>and</b>	
<input type="checkbox"/>	Patient has three or less copies of SMN2

**Renewal — spinal muscular atrophy (SMA)**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	There has been demonstrated maintenance of motor milestone function since treatment initiation
<b>and</b>	
<input type="checkbox"/>	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
<b>and</b>	
<input type="checkbox"/>	Nusinersen not to be administered in combination other SMA disease modifying treatments or gene therapy

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**Risdiplam**

**Initial application — spinal muscular atrophy (SMA)**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has genetic documentation of homozygous SMN1 gene deletion, homozygous SMN1 point mutation, or compound heterozygous mutation
<b>and</b>	
<input type="checkbox"/>	Patient is 18 years of age or under
<b>and</b>	
<input type="checkbox"/>	Patient has experienced the defined signs and symptoms of SMA type I, II or IIIa prior to three years of age
<b>or</b>	
<input type="checkbox"/>	Patient is pre-symptomatic
<b>and</b>	
<input type="checkbox"/>	Patient has three or less copies of SMN2

**Renewal — spinal muscular atrophy (SMA)**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	There has been demonstrated maintenance of motor milestone function since treatment initiation
<b>and</b>	
<input type="checkbox"/>	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
<b>and</b>	
<input type="checkbox"/>	Risdiplam not to be administered in combination other SMA disease modifying treatments or gene therapy

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**Lisdexamfetamine dimesilate**

**Initial application**

Applications only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

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

Applicant is a paediatrician or psychiatrist

or

Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing

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 the above details are correct and that in signing this form I understand I may be audited.

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

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**Dexamfetamine Sulfate**

**Initial application — ADHD in patients aged 5 years or over**  
Applications only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

ADHD (Attention Deficit and Hyperactivity Disorder) in patients aged 5 years or over  
**and**  Diagnosed according to DSM-IV or ICD 10 criteria  
**and**

Applicant is a paediatrician or psychiatrist  
**or**  Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing

**Initial application — ADHD in patients aged under 5 years**  
Applications only from a paediatrician or psychiatrist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

ADHD (Attention Deficit and Hyperactivity Disorder) in patients under 5 years of age  
**and**  Diagnosed according to DSM-IV or ICD 10 criteria

**Initial application — Narcolepsy**  
Applications only from a neurologist or respiratory specialist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The patient suffers from narcolepsy

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Methylphenidate Hydrochloride** (Rubifen; Rubifen SR; Ritalin; Ritalin SR; Methylphenidate ER - Teva)

**Initial application — ADHD in patients aged 5 years or over**

Applications only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	ADHD (Attention Deficit and Hyperactivity Disorder) in patients aged 5 years or over
<b>and</b>	<input type="checkbox"/>
	Diagnosed according to DSM-IV or ICD 10 criteria
<b>and</b>	<input type="checkbox"/>
	Applicant is a paediatrician or psychiatrist
<b>or</b>	<input type="checkbox"/>
	Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing

**Initial application — ADHD in patients aged under 5 years**

Applications only from a paediatrician or psychiatrist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	ADHD (Attention Deficit and Hyperactivity Disorder) in patients under 5 years of age
<b>and</b>	<input type="checkbox"/>
	Diagnosed according to DSM-IV or ICD 10 criteria

**Initial application — Narcolepsy\***

Applications only from a neurologist or respiratory specialist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The patient suffers from narcolepsy

Note: \*narcolepsy is not a registered indication for Methylphenidate ER – Teva.

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Methylphenidate Hydrochloride Extended Release** (Concerta; Ritalin LA)

**Initial application — ADHD**

Applications only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	ADHD (Attention Deficit and Hyperactivity Disorder)
<b>and</b>	
<input type="checkbox"/>	Diagnosed according to DSM-IV or ICD 10 criteria
<b>and</b>	
<input type="checkbox"/>	Applicant is a paediatrician or psychiatrist
<b>or</b>	
<input type="checkbox"/>	Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing
<b>and</b>	
<input type="checkbox"/>	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 difficulties with adherence
<b>or</b>	
<input type="checkbox"/>	There is significant concern regarding the risk of diversion or abuse of immediate-release methylphenidate hydrochloride

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**Modafinil**

**Initial application**

Applications only from a neurologist or respiratory specialist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The patient has a diagnosis of narcolepsy and has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more
<b>and</b>
<input type="checkbox"/> 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
<b>or</b>
<input type="checkbox"/> The patient has at least one of: cataplexy, sleep paralysis or hypnagogic hallucinations
<b>and</b>
<input type="checkbox"/> An effective dose of a subsidised formulation of methylphenidate or dexamfetamine has been trialled and discontinued because of intolerable side effects
<b>or</b>
<input type="checkbox"/> Methylphenidate and dexamfetamine are contraindicated

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**Rivastigmine patches**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The patient has been diagnosed with dementia <b>and</b> <input type="checkbox"/> The patient has experienced intolerable nausea and/or vomiting from donepezil tablets
---

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The treatment remains appropriate <b>and</b> <input type="checkbox"/> The patient has demonstrated a significant and sustained benefit from treatment
--

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**Naltrexone**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient is currently enrolled in a recognised comprehensive treatment programme for alcohol dependence <b>and</b> <input type="checkbox"/> Applicant works in or with a community Alcohol and Drug Service contracted to Health NZ or accredited against the New Zealand Alcohol and Other Drug Sector Standard or the National Mental Health Sector Standard
--

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Compliance with the medication (prescriber determined) <b>and</b> <input type="checkbox"/> Patient is still unstable and requires further treatment <b>or</b> <input type="checkbox"/> Patient achieved significant improvement but requires further treatment <b>or</b> <input type="checkbox"/> Patient is well controlled but requires maintenance therapy
--

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**Varenicline tartrate**

Note: a maximum of 12 weeks' varenicline will be subsidised on each Special Authority approval.  
This includes the 4-week 'starter' pack.

**Initial application**  
Applications from any relevant practitioner. Approvals valid for 5 months.  
**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 (see note)

**Renewal**  
Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 5 months.  
The patient must not have had an approval in the past 6 months.  
**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**

It has been 6 months since the patient's previous Special Authority was approved

**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 (see note)

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**Buprenorphine with naloxone**

**Initial application — Detoxification**

Applications from any medical practitioner. Approvals valid for 1 month.

**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  Applicant works in an opioid treatment service approved by the Ministry of Health.

**Initial application — Maintenance treatment**

Applications from any medical practitioner. Approvals valid for 12 months.

**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  Applicant works in an opioid treatment service approved by the Ministry of Health

**Renewal — Detoxification**

Current approval Number (if known):.....

Applications from any medical practitioner. Approvals valid for 1 month.

**Prerequisites**(tick boxes where appropriate)

- Patient is opioid dependent
- and  Patient has previously trialled but failed detoxification with buprenorphine with naloxone with relapse back to opioid use and another attempt is planned
- and  Patient is currently engaged with an opioid treatment service approved by the Ministry of Health
- and  Applicant works in an opioid treatment service approved by the Ministry of Health

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**Buprenorphine with naloxone** - *continued*

**Renewal — Maintenance treatment**

Current approval Number (if known):.....

Applications from any medical practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient is or has been receiving maintenance therapy with buprenorphine with naloxone (and is not receiving methadone)
<b>and</b>	
<input type="checkbox"/>	Patient is currently enrolled in an opioid substitution program in a service approved by the Ministry of Health
<b>and</b>	
<input type="checkbox"/>	Applicant works in an opioid treatment service approved by the Ministry of Health or is a medical practitioner authorised by the service to manage treatment in this patient

**Renewal — Maintenance treatment where the patient has previously had an initial application for detoxification**

Current approval Number (if known):.....

Applications from any medical practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient received but failed detoxification with buprenorphine with naloxone
<b>and</b>	
<input type="checkbox"/>	Maintenance therapy with buprenorphine with naloxone is planned (and patient will not be receiving methadone)
<b>and</b>	
<input type="checkbox"/>	Patient is currently enrolled in an opioid substitution program in a service approved by the Ministry of Health
<b>and</b>	
<input type="checkbox"/>	Applicant works in an opioid treatment service approved by the Ministry of Health

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## **Oncology Agents and Immunosuppressants**

**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER** Reg No: .....

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**Bendamustine hydrochloride**

**Initial application — CLL\***

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has chronic lymphocytic leukaemia requiring treatment
- and  Patient has ECOG performance status of 0-2
- and  Bendamustine is to be administered at a maximum dose of 100 mg/m<sup>2</sup> 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).

**Initial application — Indolent, Low-grade lymphomas**

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has indolent low grade NHL requiring treatment
- and  The 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 the above details are correct and that in signing this form I understand I may be audited.

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

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**Bendamustine hydrochloride** - *continued*

**Renewal — Indolent, Low-grade lymphomas**

Current approval Number (if known):.....

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient is refractory to or has relapsed within 12 months of rituximab in combination with bendamustine <b>and</b> <input type="checkbox"/> Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles		
<b>or</b>		
<input type="checkbox"/> Patients have not received a bendamustine regimen within the last 12 months <b>and</b> <table border="1"><tr><td><input type="checkbox"/> Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+) <b>and</b> <input type="checkbox"/> Patient has had a rituximab treatment-free interval of 12 months or more</td></tr><tr><td><b>or</b> <input type="checkbox"/> Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients</td></tr></table>	<input type="checkbox"/> Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+) <b>and</b> <input type="checkbox"/> Patient has had a rituximab treatment-free interval of 12 months or more	<b>or</b> <input type="checkbox"/> Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients
<input type="checkbox"/> Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+) <b>and</b> <input type="checkbox"/> Patient has had a rituximab treatment-free interval of 12 months or more		
<b>or</b> <input type="checkbox"/> 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/ Waldenstrom's macroglobulinaemia.

**Initial application — Hodgkin's lymphoma\***

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has Hodgkin's lymphoma requiring treatment <b>and</b> <input type="checkbox"/> Patient has a ECOG performance status of 0-2 <b>and</b> <input type="checkbox"/> Patient has received one prior line of chemotherapy <b>and</b> <input type="checkbox"/> Patient's disease relapsed or was refractory following prior chemotherapy <b>and</b> <input type="checkbox"/> 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 the above details are correct and that in signing this form I understand I may be audited.**

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

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**Mercaptopurine**

**Initial application**

Applications only from a paediatric haematologist or paediatric oncologist. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

The patient requires a total dose of less than one full 50 mg tablet per day

**Renewal**

Current approval Number (if known):.....

Applications only from a paediatric haematologist or paediatric oncologist. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

Patient still requires a total dose of less than one full 50 mg tablet per day

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Azacitidine**

**Initial application**

Applications only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

The patient has International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome

**or**

The patient has chronic myelomonocytic leukaemia (10%-29% marrow blasts without myeloproliferative disorder)

**or**

The patient has acute myeloid leukaemia with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation Classification (WHO)

**and**

The patient has performance status (WHO/ECOG) grade 0-2

**and**

The patient has an estimated life expectancy of at least 3 months

**Renewal**

Current approval Number (if known):.....

Applications only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

No evidence of disease progression

**and**

The treatment remains appropriate and patient is benefitting from treatment

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**Thalidomide**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

The patient has plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The 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.

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**Temozolomide**

**Initial application — gliomas**

Applications only from a relevant specialist. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

The patient has a glioma

**Renewal — gliomas**

Current approval Number (if known):.....

Applications only from a relevant specialist. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

Treatment remains appropriate and patient is benefitting from treatment

**Initial application — neuroendocrine tumours**

Applications only from a relevant specialist. Approvals valid for 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<sup>2</sup> per day
- and**
- Temozolomide to be discontinued at disease progression

**Renewal — neuroendocrine tumours**

Current approval Number (if known):.....

Applications only from a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- No evidence of disease progression
- and**
- The treatment remains appropriate and the patient is benefitting from treatment

**Initial application — ewing's sarcoma**

Applications only from a relevant specialist. Approvals valid for 9 months.

**Prerequisites**(tick box where appropriate)

The patient has relapsed/refractory Ewing's sarcoma

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**Temozolomide** - *continued*

**Renewal — ewing’s sarcoma**

Current approval Number (if known):.....

Applications only from a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<b>and</b>	<input type="checkbox"/> No evidence of disease progression
	<input type="checkbox"/> The treatment remains appropriate and the patient is benefitting from treatment

Note: Indication marked with a \* is an unapproved indication. Temozolomide is not subsidised for the treatment of relapsed high grade glioma.

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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**Bortezomib**

**Initial application — plasma cell dyscrasia**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The patient has plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment

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**Pegaspargase**

**Initial application — Acute lymphoblastic leukaemia**  
Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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

**Initial application — Lymphoma**  
Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months.  
**Prerequisites**(tick box where appropriate)

The patient has lymphoma requiring L-asparaginase containing protocols (e.g. SMILE)

**Renewal — Acute lymphoblastic leukaemia**  
Current approval Number (if known):.....  
Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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

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**Lenalidomide**

**Initial application — Relapsed/refractory disease**

Applications only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

Patient has relapsed or refractory multiple myeloma with progressive disease  
**and**  Patient has not previously been treated with lenalidomide  
**and**

Lenalidomide to be used as third line\* treatment for multiple myeloma  
**or**

Lenalidomide to be used as second line treatment for multiple myeloma  
**and**  The patient has experienced severe (grade 3 or higher), dose limiting, peripheral neuropathy with either bortezomib or thalidomide that precludes further treatment with either of these treatments

**and**  Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone

**Initial application — Maintenance following first-line autologous stem cell transplant (SCT)**

Applications only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

Patient has newly diagnosed symptomatic multiple myeloma and has undergone first-line treatment that included an autologous stem cell transplantation  
**and**  Patient has at least a stable disease response in the first 100 days after transplantation  
**and**  Lenalidomide maintenance is to be commenced within 6 months of transplantation  
**and**  Lenalidomide to be administered at a maximum dose of 15 mg/day

**Renewal — Relapsed/refractory disease**

Current approval Number (if known):.....

Applications only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

No evidence of disease progression  
**and**  The treatment remains appropriate and patient is benefitting from treatment

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**Lenalidomide** - *continued*

**Renewal — Maintenance following first line autologous SCT**

Current approval Number (if known):.....

Applications only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<b>and</b>	<input type="checkbox"/> No evidence of disease progression
	<input type="checkbox"/> The treatment remains appropriate and patient is benefitting from treatment

Note: Indication marked with \* is an unapproved indication. A line of treatment is considered to comprise either: a) a known therapeutic chemotherapy regimen and supportive treatments or b) a transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments. Prescriptions must be written by a registered prescriber in the lenalidomide risk management programme operated by the supplier.

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**Venetoclax**

**Initial application — relapsed/refractory chronic lymphocytic leukaemia**

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 7 months.

**Prerequisites**(tick boxes where appropriate)

- Patient has chronic lymphocytic leukaemia requiring treatment
- and  Patient has received at least one prior therapy for chronic lymphocytic leukaemia
- and  Patient has not previously received funded venetoclax
- and  The patient's disease has relapsed within 36 months of previous treatment
- 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  Patient has an ECOG performance status of 0-2

**Renewal — relapsed/refractory chronic lymphocytic leukaemia**

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- Treatment remains clinically appropriate and the patient 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

**Initial application — previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation\***

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- Patient has previously untreated chronic lymphocytic leukaemia
- and  There is documentation confirming that patient has 17p deletion by FISH testing or TP53 mutation by sequencing
- and  Patient has an ECOG performance status of 0-2

**Renewal — previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation\***

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

- The treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL)\* and B-cell prolymphocytic leukaemia (B-PLL)\*. Indications marked with \* are Unapproved indications.

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**Olaparib**

**Initial application — Ovarian cancer**

Applications only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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

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**Olaparib** - *continued*

**Renewal — Ovarian cancer**

Current approval Number (if known):.....

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Treatment remains clinically appropriate and patient is benefitting from treatment
<b>and</b>	
<input type="checkbox"/>	No evidence of progressive disease
<b>or</b>	
<input type="checkbox"/>	Evidence of residual (not progressive) disease and the patient would continue to benefit from treatment in the clinician's opinion
<b>and</b>	
<input type="checkbox"/>	Treatment to be administered as maintenance treatment
<b>and</b>	
<input type="checkbox"/>	Treatment not to be administered in combination with other chemotherapy
<b>and</b>	
<input type="checkbox"/>	Patient has received one line** of previous treatment with platinum-based chemotherapy
<b>and</b>	
<input type="checkbox"/>	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
<b>or</b>	
<input type="checkbox"/>	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.

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**Ibrutinib**

**Initial application — chronic lymphocytic leukaemia (CLL)**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has chronic lymphocytic leukaemia (CLL) requiring therapy										
<b>and</b>											
<input type="checkbox"/>	Patient has not previously received funded ibrutinib										
<b>and</b>											
<input type="checkbox"/>	Ibrutinib is to be used as monotherapy										
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<table border="0"> <tr> <td><input type="checkbox"/></td> <td>There is documentation confirming that patient has 17p deletion or TP53 mutation</td> </tr> <tr> <td><b>and</b></td> <td></td> </tr> <tr> <td><input type="checkbox"/></td> <td>Patient has experienced intolerable side effects with venetoclax monotherapy</td> </tr> </table>		<input type="checkbox"/>	There is documentation confirming that patient has 17p deletion or TP53 mutation	<b>and</b>		<input type="checkbox"/>	Patient has experienced intolerable side effects with venetoclax monotherapy				
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<table border="0"> <tr> <td><input type="checkbox"/></td> <td>Patient has received at least one prior immunochemotherapy for CLL</td> </tr> <tr> <td><b>and</b></td> <td></td> </tr> <tr> <td><input type="checkbox"/></td> <td>Patient's CLL has relapsed within 36 months of previous treatment</td> </tr> <tr> <td><b>and</b></td> <td></td> </tr> <tr> <td><input type="checkbox"/></td> <td>Patient has experienced intolerable side effects with venetoclax in combination with rituximab regimen</td> </tr> </table>		<input type="checkbox"/>	Patient has received at least one prior immunochemotherapy for CLL	<b>and</b>		<input type="checkbox"/>	Patient's CLL has relapsed within 36 months of previous treatment	<b>and</b>		<input type="checkbox"/>	Patient has experienced intolerable side effects with venetoclax in combination with rituximab regimen
<input type="checkbox"/>	Patient has received at least one prior immunochemotherapy for CLL										
<b>and</b>											
<input type="checkbox"/>	Patient's CLL has relapsed within 36 months of previous treatment										
<b>and</b>											
<input type="checkbox"/>	Patient has experienced intolerable side effects with venetoclax in combination with rituximab regimen										
<b>or</b>											
<input type="checkbox"/>	Patient's CLL is refractory to or has relapsed within 36 months of a venetoclax regimen										

**Renewal — chronic lymphocytic leukaemia (CLL)**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	No evidence of clinical disease progression
<b>and</b>	
<input type="checkbox"/>	The treatment remains appropriate and the patient is benefitting from treatment

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL) and B-cell prolymphocytic leukaemia (B-PLL)\*. Indications marked with \* are Unapproved indications.

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**Niraparib**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 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

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

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**Lenalidomide**

**Initial application — Plasma cell dyscrasia**  
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.  
**Prerequisites**(tick boxes where appropriate)

Patient has plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment

**and**

Patient is not refractory to prior lenalidomide use

**Initial application — Myelodysplastic syndrome**  
Applications from any relevant practitioner. Approvals valid for 6 months.  
**Prerequisites**(tick boxes where appropriate)

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

**Renewal — Myelodysplastic syndrome**  
Current approval Number (if known):.....  
Applications from any relevant practitioner. Approvals valid for 12 months.  
**Prerequisites**(tick boxes where appropriate)

Patient has not needed a transfusion in the last 4 months

**and**

No evidence of disease progression

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Pomalidomide**

**Initial application — Relapsed/refractory plasma cell dyscrasia**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<p><input type="checkbox"/> Patient has relapsed or refractory plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment</p> <p><b>and</b></p> <p><input type="checkbox"/> Patient has not received prior funded pomalidomide</p>
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**Renewal — Relapsed/refractory plasma cell dyscrasia**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

There is no evidence of disease progression

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**Dasatinib**

**Initial application**

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis or accelerated phase
or	
<input type="checkbox"/>	The patient has a diagnosis of Philadelphia chromosome-positive acute lymphoid leukaemia (Ph+ ALL)
or	
<input type="checkbox"/>	The patient has a diagnosis of CML in chronic phase
and	
<input type="checkbox"/>	Patient has documented treatment failure* with imatinib
or	
<input type="checkbox"/>	Patient has experienced treatment-limiting toxicity with imatinib precluding further treatment with imatinib
or	
<input type="checkbox"/>	Patient has high-risk chronic-phase CML defined by the Sokal or EURO scoring system

**Renewal**

Current approval Number (if known):.....

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Lack of treatment failure while on dasatinib*
and	
<input type="checkbox"/>	Dasatinib treatment remains appropriate and the patient is benefiting from treatment

Note: \*treatment failure for CML as defined by Leukaemia Net Guidelines.

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**Erlotinib**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC)
<b>and</b>	
<input type="checkbox"/>	There is documentation confirming that the disease expresses activating mutations of EGFR
<b>and</b>	
<input type="checkbox"/>	Patient is treatment naive
<b>or</b>	
<input type="checkbox"/>	Patient has received prior treatment in the adjuvant setting and/or while awaiting EGFR results
<b>or</b>	
<input type="checkbox"/>	The patient has discontinued osimertinib or gefitinib due to intolerance
<b>and</b>	
<input type="checkbox"/>	The cancer did not progress while on osimertinib or gefitinib

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

Radiological assessment (preferably including CT scan) indicates NSCLC has not progressed

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**Sunitinib**

**Initial application — RCC**

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

The patient has metastatic renal cell carcinoma

and

The patient is treatment naive

or

The patient has only received prior cytokine treatment

or

The patient has only received prior treatment with an investigational agent within the confines of a bona fide clinical trial which has Ethics Committee approval

or

The patient has discontinued pazopanib within 3 months of starting treatment due to intolerance

and

The cancer did not progress whilst on pazopanib

and

The patient has good performance status (WHO/ECOG grade 0-2)

and

The disease is of predominant clear cell histology

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

and

Sunitinib to be used for a maximum of 2 cycles

**Initial application — GIST**

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**Sunitinib - continued**

**Renewal — RCC**

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

No evidence of disease progression  
and  
 The treatment remains appropriate and the patient is benefiting from treatment

Note: Sunitinib treatment should be stopped if disease progresses.

Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6

**Renewal — GIST**

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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

Note: 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.

**Renewal — GIST pandemic circumstances**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

The patient has unresectable or metastatic malignant gastrointestinal stromal (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 Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector

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**Pazopanib**

**Initial application**

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

The patient has metastatic renal cell carcinoma

and

The patient is treatment naive

or

The patient has only received prior cytokine treatment

or

The patient has discontinued sunitinib within 3 months of starting treatment due to intolerance

and

The cancer did not progress whilst on sunitinib

and

The patient has good performance status (WHO/ECOG grade 0-2)

and

The disease is of predominant clear cell histology

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

and

Pazopanib to be used for a maximum of 3 months

**Renewal**

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

No evidence of disease progression

and

The treatment remains appropriate and the patient is benefiting from treatment

Note: Pazopanib treatment should be stopped if disease progresses.  
Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6.

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**Gefitinib**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC)
<b>and</b>	
<input type="checkbox"/>	Patient is treatment naive
<b>or</b>	
<input type="checkbox"/>	Patient has received prior treatment in the adjuvant setting and/or while awaiting EGFR results
<b>or</b>	
<input type="checkbox"/>	The patient has discontinued osimertinib or erlotinib due to intolerance
<b>and</b>	
<input type="checkbox"/>	The cancer did not progress whilst on osimertinib or erlotinib
<b>and</b>	
<input type="checkbox"/>	There is documentation confirming that disease expresses activating mutations of EGFR

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

Radiological assessment (preferably including CT scan) indicates NSCLC has not progressed

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**Nilotinib**

**Initial application**

Applications only from a haematologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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.

**Renewal**

Current approval Number (if known):.....

Applications only from a haematologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

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**Ruxolitinib**

**Initial application**

Applications only from a haematologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal**

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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

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**Alectinib**

**Initial application**

Applications only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has locally advanced, or metastatic, unresectable, non-small cell lung cancer
<b>and</b>	
<input type="checkbox"/>	There is documentation confirming that the patient has an ALK tyrosine kinase gene rearrangement using an appropriate ALK test
<b>and</b>	
<input type="checkbox"/>	Patient has an ECOG performance score of 0-2

**Renewal**

Current approval Number (if known):.....

Applications only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	No evidence of progressive disease according to RECIST criteria
<b>and</b>	
<input type="checkbox"/>	The patient is benefitting from and tolerating treatment

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**Palbociclib (Ibrance)**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 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

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

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**Midostaurin**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 9 months.

**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

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**Ribociclib**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 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  
**or**

Patient commenced treatment with ribociclib in combination with an endocrine partner prior to 1 July 2024  
**and**  There is no evidence of progressive 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

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

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**Lenvatinib**

**Initial application — thyroid cancer**

Applications from any relevant practitioner. Approvals valid for 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 suppressed

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

**Renewal — thyroid cancer**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

There is no evidence of disease progression

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**Lenvatinib - continued**

**Initial application — unresectable hepatocellular carcinoma**

Applications from any relevant practitioner. Approvals valid for 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

**Renewal — unresectable hepatocellular carcinoma**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

- There is no evidence of disease progression

**Initial application — renal cell carcinoma**

Applications from any relevant practitioner. Approvals valid for 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

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**Lenvatinib** - *continued*

**Renewal — renal cell carcinoma**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 4 months.

**Prerequisites**(tick box where appropriate)

There is no evidence of disease progression

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**Osimertinib**

**Initial application — NSCLC – first line**

Applications from any relevant practitioner. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient is currently on treatment with osimertinib and met all remaining criteria prior to commencing treatment
or	
<input type="checkbox"/>	Patient has locally advanced or metastatic, incurable, non-squamous non-small cell lung cancer (NSCLC)
and	
<input type="checkbox"/>	Patient is treatment naïve
or	
<input type="checkbox"/>	Patient has received prior chemotherapy in the adjuvant setting and/or while awaiting EGFR results
or	
<input type="checkbox"/>	The patient has discontinued gefitinib or erlotinib due to intolerance
and	
<input type="checkbox"/>	The cancer did not progress while on gefitinib or erlotinib
and	
<input type="checkbox"/>	There is documentation confirming that the cancer expresses activating mutations of EGFR
and	
<input type="checkbox"/>	Patient has an ECOG performance status 0-3
and	
<input type="checkbox"/>	Baseline measurement of overall tumour burden is documented clinically and radiologically

**Renewal — NSCLC – first line**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

<input type="checkbox"/>	Response to or stable disease with treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period
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**Osimertinib - continued**

**Initial application — NSCLC – second line**

Applications from any relevant practitioner. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient is currently on treatment with osimertinib and met all remaining criteria prior to commencing treatment
<b>or</b>	
<input type="checkbox"/>	Patient has locally advanced or metastatic, incurable, non-squamous non-small cell lung cancer (NSCLC)
<b>and</b>	<input type="checkbox"/>
	Patient has an ECOG performance status 0-3
<b>and</b>	<input type="checkbox"/>
	The patient must have received previous treatment with erlotinib or gefitinib
<b>and</b>	<input type="checkbox"/>
	There is documentation confirming that the cancer expresses T790M mutation of EGFR following progression on or after erlotinib or gefitinib
<b>and</b>	<input type="checkbox"/>
	The treatment must be given as monotherapy
<b>and</b>	<input type="checkbox"/>
	Baseline measurement of overall tumour burden is documented clinically and radiologically

**Renewal — NSCLC – second line**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

<input type="checkbox"/>	Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period
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**Octreotide long-acting**

**Initial application — Malignant Bowel Obstruction**

Applications from any relevant practitioner. Approvals valid for 2 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has nausea* and vomiting* due to malignant bowel obstruction*
<b>and</b>	
<input type="checkbox"/>	Treatment with antiemetics, rehydration, antimuscarinic agents, corticosteroids and analgesics for at least 48 hours has failed
<b>and</b>	
<input type="checkbox"/>	Octreotide to be given at a maximum dose 1500 mcg daily for up to 4 weeks

Note: Indications marked with \* are unapproved indications.

**Renewal — Malignant Bowel Obstruction**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 3 months.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

**Initial application — Acromegaly**

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has acromegaly
<b>and</b>	
<input type="checkbox"/>	Treatment with surgery, radiotherapy and a dopamine agonist has failed
<b>or</b>	
<input type="checkbox"/>	Treatment with octreotide is for an interim period while awaiting the effects of radiotherapy and a dopamine agonist has failed
<b>or</b>	
<input type="checkbox"/>	The patient is unwilling, or unable, to undergo surgery and/or radiotherapy

**Renewal — Acromegaly**

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	IGF1 levels have decreased since starting octreotide
<b>and</b>	
<input type="checkbox"/>	The treatment remains appropriate and the patient is benefiting from treatment

Note: In patients with Acromegaly octreotide treatment should be discontinued if IGF1 levels have not decreased after 3 months treatment. In patients treated with radiotherapy octreotide treatment should be withdrawn every 2 years, for 1 month, for assessment of remission. Octreotide treatment should be stopped where there is biochemical evidence of remission (normal IGF1 levels) following octreotide treatment withdrawal for at least 4 weeks

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Octreotide long-acting - continued**

**Renewal — Acromegaly - pandemic circumstances**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

Patient has acromegaly

**and**

The patient is clinically benefiting from treatment and continued treatment remains appropriate

**and**

The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector

**Initial application — Other Indications**

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years.

**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**

Patient has failed surgery

**or**

Patient in metastatic disease after H2 antagonists (or proton pump inhibitors) have failed

**or**

Insulinomas

**and**

Surgery is contraindicated or has failed

**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

Note: The use of octreotide in patients with fistulae, oesophageal varices, miscellaneous diarrhoea and hypotension will not be funded as a Special Authority item

**Renewal — Other Indications**

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

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**Octreotide long-acting** - *continued*

**Initial application — pre-operative acromegaly**

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Abiraterone acetate**

**Initial application**

Applications only from a medical oncologist, radiation oncologist, urologist or medical practitioner on the recommendation of a medical oncologist, radiation oncologist or urologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal — abiraterone acetate**

Current approval Number (if known):.....

Applications only from a medical oncologist, radiation oncologist, urologist or medical practitioner on the recommendation of a medical oncologist, radiation oncologist or urologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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 the above details are correct and that in signing this form I understand I may be audited.**

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**Abiraterone acetate** - *continued*

**Renewal — pandemic circumstances**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The patient is clinically benefiting from treatment and continued treatment remains appropriate
<b>and</b> <input type="checkbox"/> Abiraterone acetate to be discontinued at progression
<b>and</b> <input type="checkbox"/> No initiation of taxane chemotherapy with abiraterone
<b>and</b> <input type="checkbox"/> The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Fulvestrant**

**Initial application**

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has oestrogen-receptor positive locally advanced or metastatic breast cancer
<b>and</b>	
<input type="checkbox"/>	Patient has disease progression following prior treatment with an aromatase inhibitor or tamoxifen for their locally advanced or metastatic disease
<b>and</b>	
<input type="checkbox"/>	Treatment to be given at a dose of 500 mg monthly following loading doses
<b>and</b>	
<input type="checkbox"/>	Treatment to be discontinued at disease progression

**Renewal**

Current approval Number (if known):.....

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Treatment remains appropriate and patient is benefitting from treatment
<b>and</b>	
<input type="checkbox"/>	Treatment to be given at a dose of 500 mg monthly
<b>and</b>	
<input type="checkbox"/>	There is no evidence of disease progression

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**Etanercept**

**Initial application — adult-onset Still's disease**

Applications only from a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

The patient has had an initial Special Authority approval for adalimumab 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 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 anti-inflammatory drugs (NSAIDs) and methotrexate

and

Patient has persistent symptoms of disabling poorly controlled and active disease

**Renewal — adult-onset Still's disease**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 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

The patient has a sustained improvement in inflammatory markers and functional status

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Etanercept - continued**

**Initial application — ankylosing spondylitis**

Applications only from a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis

**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 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**

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)

**or**

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**

A 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 initial application.

Average normal chest expansion corrected for age and gender:

- 18-24 years - Male: 7.0 cm; Female: 5.5 cm
- 25-34 years - Male: 7.5 cm; Female: 5.5 cm
- 35-44 years - Male: 6.5 cm; Female: 4.5 cm
- 45-54 years - Male: 6.0 cm; Female: 5.0 cm
- 55-64 years - Male: 5.5 cm; Female: 4.0 cm
- 65-74 years - Male: 4.0 cm; Female: 4.0 cm
- 75+ years - Male: 3.0 cm; Female: 2.5 cm

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**Etanercept - continued**

**Renewal — ankylosing spondylitis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 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 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

**Initial application — polyarticular course juvenile idiopathic arthritis**

Applications only from a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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**Etanercept - continued**

**Renewal — polyarticular course juvenile idiopathic arthritis**

Current approval Number (if known):.....

Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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 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

**Initial application — oligoarticular course juvenile idiopathic arthritis**

Applications only from a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

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**Etanercept** - *continued*

**Renewal — oligoarticular course juvenile idiopathic arthritis**

Current approval Number (if known):.....

Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<b>and</b>	<input type="checkbox"/> Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
	<b>or</b>
<input type="checkbox"/>	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
<input type="checkbox"/>	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 the above details are correct and that in signing this form I understand I may be audited.

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**Etanercept - continued**

**Initial application — psoriatic arthritis**

Applications only from a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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 the above details are correct and that in signing this form I understand I may be audited.

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**Etanercept - continued**

**Renewal — psoriatic arthritis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 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 every 7 days

**Initial application — pyoderma gangrenosum**

Applications only from a dermatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

- Patient has pyoderma gangrenosum\*  
and  
 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response  
and  
 A maximum of 8 doses

Note: Indications marked with \* are unapproved indications.

**Renewal — pyoderma gangrenosum**

Current approval Number (if known):.....

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

- Patient has shown clinical improvement  
and  
 Patient continues to require treatment  
and  
 A maximum of 8 doses

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Etanercept - continued**

**Initial application — Arthritis - rheumatoid**

Applications only from a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Etanercept** - *continued*

**Renewal — Arthritis - rheumatoid**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
<b>and</b>
<input type="checkbox"/> 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
<b>or</b>
<input type="checkbox"/> 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
<b>and</b>
<input type="checkbox"/> Etanercept to be administered at doses no greater than 50 mg every 7 days

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Etanercept - continued**

**Initial application — severe chronic plaque psoriasis**

Applications only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The patient has had an initial Special Authority approval for adalimumab for severe chronic plaque psoriasis
<b>and</b>
<input type="checkbox"/> The patient has experienced intolerable side effects from adalimumab
<b>or</b>
<input type="checkbox"/> The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe chronic plaque psoriasis
<b>or</b>
<input type="checkbox"/> 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
<b>or</b>
<input type="checkbox"/> 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
<b>or</b>
<input type="checkbox"/> 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
<b>and</b>
<input type="checkbox"/> 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
<b>and</b>
<input type="checkbox"/> 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
<b>and</b>
<input type="checkbox"/> The most recent PASI or DLQI assessment is no more than 1 month old at the time of application

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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**Etanercept** - *continued*

**Renewal — severe chronic plaque psoriasis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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-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-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

Note: A treatment course is defined as a minimum of 12 weeks of etanercept treatment

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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**Etanercept - continued**

**Initial application — undifferentiated spondyloarthritis**

Applications only from a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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.

**Renewal — undifferentiated spondyloarthritis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 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

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**Rituximab** (Mabthera)

**Initial application — rheumatoid arthritis - TNF inhibitors contraindicated**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

- 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 ciclosporin
- 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 the above details are correct and that in signing this form I understand I may be audited.

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

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**Rituximab** (Mabthera) - *continued*

**Initial application — rheumatoid arthritis - prior TNF inhibitor use**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal — rheumatoid arthritis - re-treatment in 'partial responders' to rituximab**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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**Rituximab** (Mabthera) - *continued*

**Renewal — rheumatoid arthritis - re-treatment in 'responders' to rituximab**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<b>or</b>	<input type="checkbox"/> 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
	<input type="checkbox"/> 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
<b>and</b>	<input type="checkbox"/> Rituximab re-treatment not to be given within 6 months of the previous course of treatment
<b>and</b>	<input type="checkbox"/> Rituximab to be used as an adjunct to methotrexate or leflunomide therapy
<b>or</b>	
<b>and</b>	<input type="checkbox"/> Maximum of two 1,000 mg infusions of rituximab given two weeks apart

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Adalimumab (Humira - Alternative brand)**

**Initial application — Behcet’s disease – severe**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Renewal — Behcet’s disease – severe**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Initial application — Hidradenitis suppurativa**

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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 the above details are correct and that in signing this form I understand I may be audited.**

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Hidradenitis suppurativa**

Current approval Number (if known):.....

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

**Initial application — Psoriasis - severe chronic plaque**

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Psoriasis - severe chronic plaque**

Current approval Number (if known):.....

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

**Initial application — Pyoderma gangrenosum**

Applications only from a dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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 the above details are correct and that in signing this form I understand I may be audited.**

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Pyoderma gangrenosum**

Current approval Number (if known):.....

Applications only from a dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has demonstrated clinical improvement and continues to require treatment
- and**
- A maximum of 8 doses

**Initial application — Crohn’s disease - adult**

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Renewal — Crohn’s disease - adult**

Current approval Number (if known):.....

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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 the above details are correct and that in signing this form I understand I may be audited.**

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

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**Adalimumab (Humira - Alternative brand) - continued**

**Initial application — Crohn's disease - children**

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Renewal — Crohn's disease - children**

Current approval Number (if known):.....

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Initial application — Crohn's disease - fistulising**

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Crohn’s disease - fistulising**

Current approval Number (if known):.....

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Initial application — Ocular inflammation – chronic**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- 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

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Ocular inflammation – chronic**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The patient has had a good clinical response following 12 weeks' initial treatment <b>or</b> <input type="checkbox"/> 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) <b>or</b> <input type="checkbox"/> 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
<b>and</b>
<input type="checkbox"/> Adalimumab to be administered at doses no greater than 40 mg every 14 days

**Initial application — Ocular inflammation – severe**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> 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 <b>or</b> <input type="checkbox"/> 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 <b>or</b> <input type="checkbox"/> Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment
<b>and</b>
<input type="checkbox"/> Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication
<b>and</b>
<input type="checkbox"/> Adalimumab to be administered at doses no greater than 40 mg every 14 days

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Ocular inflammation – severe**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

and

Adalimumab to be administered at doses no greater than 40 mg every 14 days

**Initial application — ankylosing spondylitis**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal — ankylosing spondylitis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

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**Adalimumab (Humira - Alternative brand) - continued**

**Initial application — Arthritis – oligoarticular course juvenile idiopathic**  
Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Renewal — Arthritis – oligoarticular course juvenile idiopathic**

Current approval Number (if known):.....

Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

- The patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

**Initial application — Arthritis - polyarticular course juvenile idiopathic**

Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Renewal — Arthritis - polyarticular course juvenile idiopathic**

Current approval Number (if known):.....

Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

- The patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

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**Adalimumab (Humira - Alternative brand) - continued**

**Initial application — Arthritis - psoriatic**

Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Renewal — Arthritis - psoriatic**

Current approval Number (if known):.....

Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Initial application — Arthritis – rheumatoid**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Arthritis – rheumatoid**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

**Initial application — Still's disease – adult-onset (AOSD)**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal — Still's disease – adult-onset (AOSD)**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

The patient has demonstrated a sustained improvement in inflammatory markers and functional status

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**Omalizumab**

**Initial application — severe asthma**

Applications only from a respiratory specialist or clinical immunologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

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**Omalizumab** - continued

**Initial application — severe chronic spontaneous urticaria**

Applications only from a clinical immunologist or dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

**or**

Patient has a Urticaria Control Test (UCT) of 8 or less

**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

**Renewal — severe asthma**

Current approval Number (if known):.....

Applications only from a clinical immunologist or respiratory specialist. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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

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**Omalizumab** - *continued*

**Renewal — severe chronic spontaneous urticaria**

Current approval Number (if known):.....

Applications only from a clinical immunologist or dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has previously adequately responded* to 6 doses of omalizumab
<b>or</b>	
<input type="checkbox"/>	Patient has previously had a complete response* to 6 doses of omalizumab
<b>and</b>	
<input type="checkbox"/>	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.

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**Siltuximab**

**Initial application**

Applications only from a haematologist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has severe HHV-8 negative idiopathic multicentric Castleman's Disease
<b>and</b>	
<input type="checkbox"/>	Treatment with an adequate trial of corticosteroids has proven ineffective
<b>and</b>	
<input type="checkbox"/>	Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks

**Renewal**

Current approval Number (if known):.....

Applications only from a haematologist or rheumatologist. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

<input type="checkbox"/>	The treatment remains appropriate and the patient has sustained improvement in inflammatory markers and functional status
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**Pertuzumab**

**Initial application — metastatic breast cancer**

Applications from any relevant practitioner. Approvals valid for 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 naïve

**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

**Renewal — metastatic breast cancer**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

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**Obinutuzumab**

**Initial application — chronic lymphocytic leukaemia**

Applications only from a haematologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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.

\* Neutrophil greater than or equal to  $1.5 \times 10^9/L$  and platelets greater than or equal to  $75 \times 10^9/L$ .

**Initial application — follicular / marginal zone lymphoma**

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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

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**Obinutuzumab** - *continued*

**Renewal — follicular / marginal zone lymphoma**

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 24 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has no evidence of disease progression following obinutuzumab induction therapy
<b>and</b> <input type="checkbox"/>	Obinutuzumab to be administered at a maximum of 1000 mg every 2 months for a maximum of 2 years
<b>and</b> <input type="checkbox"/>	Obinutuzumab to be discontinued at disease progression

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**Cetuximab**

**Initial application — head and neck cancer, locally advanced**

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has locally advanced, non-metastatic, squamous cell cancer of the head and neck
and	
<input type="checkbox"/>	Cisplatin is contraindicated or has resulted in intolerable side effects
and	
<input type="checkbox"/>	Patient has an ECOG performance score of 0-2
and	
<input type="checkbox"/>	To be administered in combination with radiation therapy

**Initial application — colorectal cancer, metastatic**

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has metastatic colorectal cancer located on the left side of the colon (see Note)
and	
<input type="checkbox"/>	There is documentation confirming disease is RAS and BRAF wild-type
and	
<input type="checkbox"/>	Patient has an ECOG performance score of 0-2
and	
<input type="checkbox"/>	Patient has not received prior funded treatment with cetuximab
and	
<input type="checkbox"/>	Cetuximab is to be used in combination with chemotherapy
or	
<input type="checkbox"/>	Chemotherapy is determined to not be in the best interest of the patient based on clinician assessment

**Renewal — colorectal cancer, metastatic**

Current approval Number (if known):.....

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

There is 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.

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**Aflibercept**

**Initial application — wet age related macular degeneration**

Applications only from an ophthalmologist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

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

**Initial application — diabetic macular oedema**

Applications only from an ophthalmologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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

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**Aflibercept** - *continued*

**Renewal — wet age related macular degeneration**

Current approval Number (if known):.....

Applications only from an ophthalmologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Documented benefit must be demonstrated to continue
<b>and</b>	
<input type="checkbox"/>	Patient's vision is 6/36 or better on the Snellen visual acuity score
<b>and</b>	
<input type="checkbox"/>	There is no structural damage to the central fovea of the treated eye

**Renewal — diabetic macular oedema**

Current approval Number (if known):.....

Applications only from an ophthalmologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	There is stability or two lines of Snellen visual acuity gain
<b>and</b>	
<input type="checkbox"/>	There is structural improvement on OCT scan (with reduction in intra-retinal cysts, central retinal thickness, and sub-retinal fluid)
<b>and</b>	
<input type="checkbox"/>	Patient's vision is 6/36 or better on the Snellen visual acuity score
<b>and</b>	
<input type="checkbox"/>	There is no centre-involving sub-retinal fibrosis or foveal atrophy
<b>and</b>	
<input type="checkbox"/>	After each consecutive 12 months treatment with (2nd line anti-VEGF agent), patient has retrialled with at least one injection of bevacizumab and had no response

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**Secukinumab**

**Initial application — severe chronic plaque psoriasis – second-line biologic**

Applications only from a dermatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

The patient has had an initial Special Authority approval for adalimumab or etanercept, or has trialed 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

**Initial application — severe chronic plaque psoriasis – first-line biologic**

Applications only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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.

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**Secukinumab - continued**

**Renewal — severe chronic plaque psoriasis – first and second-line biologic**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

**Initial application — ankylosing spondylitis – second-line biologic**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal — ankylosing spondylitis – second-line biologic**

Current approval Number (if known):.....

Applications only from a rheumatologist or medical practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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 150 mg monthly

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**Secukinumab - continued**

**Initial application — psoriatic arthritis**

Applications only from a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has had an initial Special Authority approval for adalimumab, etanercept or infliximab for psoriatic arthritis
<b>and</b>
<input type="checkbox"/> Patient has experienced intolerable side effects from adalimumab, etanercept or infliximab
<b>or</b>
<input type="checkbox"/> Patient has received insufficient benefit from adalimumab, etanercept or infliximab to meet the renewal criteria for adalimumab, etanercept or infliximab for psoriatic arthritis
<b>or</b>
<input type="checkbox"/> Patient has had severe active psoriatic arthritis for six months duration or longer
<b>and</b>
<input type="checkbox"/> 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
<b>and</b>
<input type="checkbox"/> 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)
<b>and</b>
<input type="checkbox"/> Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints
<b>or</b>
<input type="checkbox"/> 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
<b>and</b>
<input type="checkbox"/> 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
<b>or</b>
<input type="checkbox"/> Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour
<b>or</b>
<input type="checkbox"/> 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

**Renewal — psoriatic arthritis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> 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
<b>or</b>
<input type="checkbox"/> 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
<b>and</b>
<input type="checkbox"/> Secukinumab to be administered at doses no greater than 300 mg monthly

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## SA2402 - Infliximab

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**Infliximab**

**Initial application — Crohn’s disease (adults)**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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 has experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and corticosteroids

**Renewal — Crohn’s disease (adults)**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019

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**Infliximab - continued**

**Initial application — Crohn’s disease (children)**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal — Crohn’s disease (children)**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019

**Initial application — Graft vs host disease**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

Patient has steroid-refractory acute graft vs. host disease of the gut

**Initial application — Pulmonary sarcoidosis**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

Patient has life-threatening pulmonary sarcoidosis diagnosed by a multidisciplinary team that is refractory to other treatments

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**Infliximab** - continued

**Initial application — acute fulminant ulcerative colitis**

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 weeks.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has acute, fulminant ulcerative colitis
<b>and</b>	
<input type="checkbox"/>	Treatment with intravenous or high dose oral corticosteroids has not been successful

**Initial application — ankylosing spondylitis**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis
<b>and</b>	
<input type="checkbox"/>	The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept
<b>or</b>	
<input type="checkbox"/>	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

**Renewal — ankylosing spondylitis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	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
<b>and</b>	
<input type="checkbox"/>	Physician considers that the patient has benefited from treatment and that continued treatment is appropriate
<b>and</b>	
<input type="checkbox"/>	Infliximab to be administered at doses no greater than 5 mg/kg every 6-8 weeks

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**Infliximab - continued**

**Initial application — chronic ocular inflammation**

Applications from any relevant practitioner. Approvals valid for 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 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

**Renewal — chronic ocular inflammation**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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.

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**Infliximab - continued**

**Initial application — fistulising Crohn’s disease**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has confirmed Crohn’s disease
<b>and</b>
<input type="checkbox"/> Patient has one or more complex externally draining enterocutaneous fistula(e)
<b>or</b>
<input type="checkbox"/> Patient has one or more rectovaginal fistula(e)
<b>or</b>
<input type="checkbox"/> Patient has complex peri-anal fistula

**Renewal — fistulising Crohn’s disease**

Current approval Number (if known):.....

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The number of open draining fistulae have decreased from baseline by at least 50%
<b>or</b>
<input type="checkbox"/> 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
<b>and</b>
<input type="checkbox"/> 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. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019

**Initial application — neurosarcoidosis**

Applications only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has been diagnosed with neurosarcoidosis by a multidisciplinary team
<b>and</b>
<input type="checkbox"/> Patient has CNS involvement
<b>and</b>
<input type="checkbox"/> Patient has steroid-refractory disease
<b>and</b>
<input type="checkbox"/> IV cyclophosphamide has been tried
<b>or</b>
<input type="checkbox"/> Treatment with IV cyclophosphamide is clinically inappropriate

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**Infliximab** - *continued*

**Renewal — neurosarcoidosis**

Current approval Number (if known):.....

Applications only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> A withdrawal period has been tried and the patient has relapsed
or
<input type="checkbox"/> A withdrawal period has been considered but would not be clinically appropriate
and
<input type="checkbox"/> There has been a marked reduction in prednisone dose
and
<input type="checkbox"/> There has been an improvement in MRI appearances
or
<input type="checkbox"/> Marked improvement in other symptomology

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**Infliximab** - continued

**Initial application — plaque psoriasis**

Applications only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

The 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, ciclosporin, 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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**Infliximab** - continued

**Renewal — plaque psoriasis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

	<input type="checkbox"/>	Patient had "whole body" severe chronic plaque psoriasis at the start of treatment
<b>and</b>	<input type="checkbox"/>	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
<b>or</b>		
	<input type="checkbox"/>	Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment
<b>and</b>	<input type="checkbox"/>	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
<b>or</b>	<input type="checkbox"/>	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
<b>or</b>		
	<input type="checkbox"/>	Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment
<b>and</b>	<input type="checkbox"/>	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
<b>or</b>	<input type="checkbox"/>	Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing infliximab
<b>and</b>	<input type="checkbox"/>	Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks

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**Infliximab** - continued

**Initial application — previous use**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

Patient was being treated with infliximab prior to 1 February 2019

**and**

Rheumatoid arthritis

**or**

Ankylosing spondylitis

**or**

Psoriatic arthritis

**or**

Severe ocular inflammation

**or**

Chronic ocular inflammation

**or**

Crohn's disease (adults)

**or**

Crohn's disease (children)

**or**

Fistulising Crohn's disease

**or**

Severe fulminant ulcerative colitis

**or**

Severe ulcerative colitis

**or**

Plaque psoriasis

**or**

Neurosarcoidosis

**or**

Severe Behcet's disease

**Initial application — psoriatic arthritis**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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 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

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**Infliximab** - *continued*

**Renewal — psoriatic arthritis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	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
<b>or</b>	
<input type="checkbox"/>	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
<b>and</b>	
<input type="checkbox"/>	Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks

**Initial application — rheumatoid arthritis**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis
<b>and</b>	
<input type="checkbox"/>	The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept
<b>or</b>	
<input type="checkbox"/>	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
<b>and</b>	
<input type="checkbox"/>	Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

**Renewal — rheumatoid arthritis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
<b>and</b>	
<input type="checkbox"/>	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
<b>or</b>	
<input type="checkbox"/>	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
<b>and</b>	
<input type="checkbox"/>	Infliximab to be administered at doses no greater than 3 mg/kg every 8 weeks

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**Infliximab** - *continued*

**Initial application — severe Behcet’s disease**

Applications from any relevant practitioner. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has severe Behcet’s disease which is significantly impacting the patient’s quality of life (see Notes)
<b>and</b>	
<input type="checkbox"/>	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)
<b>or</b>	
<input type="checkbox"/>	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)
<b>and</b>	
<input type="checkbox"/>	The patient is experiencing significant loss of quality of life

Note: 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. 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.

**Renewal — severe Behcet’s disease**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has had a good clinical response to initial treatment with measurably improved quality of life
<b>and</b>	
<input type="checkbox"/>	Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks

**Renewal — fulminant ulcerative colitis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months
<b>and</b>	
<input type="checkbox"/>	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. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019

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**Infliximab** - continued

**Initial application — severe ocular inflammation**

Applications from any relevant practitioner. Approvals valid for 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

**Renewal — severe ocular inflammation**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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.

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**Infliximab** - *continued*

**Initial application — ulcerative colitis**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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 tried but has experienced an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and systemic corticosteroids

**Renewal — ulcerative colitis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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 10 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. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019

**Initial application — pyoderma gangrenosum**

Applications only from a dermatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

Patient has pyoderma gangrenosum\*

**and**

Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response

**and**

A maximum of 8 doses

Note: Note: Indications marked with \* are unapproved indications.

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**Infliximab** - *continued*

**Renewal — pyoderma gangrenosum**

Current approval Number (if known):.....

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

- Patient has shown clinical improvement
- and  Patient continues to require treatment
- and  A maximum of 8 doses

**Initial application — inflammatory bowel arthritis – axial**

Applications from any relevant practitioner. Approvals valid for 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's disease has not responded adequately 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

**Renewal — inflammatory bowel arthritis – axial**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

- 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

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**Infliximab** - *continued*

**Initial application — inflammatory bowel arthritis – peripheral**

Applications from any relevant practitioner. Approvals valid for 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

**Renewal — inflammatory bowel arthritis – peripheral**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

**SA2404 - Tocilizumab**

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**Tocilizumab**

**Initial application — cytokine release syndrome**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**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

**Initial application — previous use**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

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**Tocilizumab** - continued

**Initial application — Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

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**Tocilizumab - continued**

**Initial application — Rheumatoid Arthritis**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	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
<b>and</b>	
<input type="checkbox"/>	Tocilizumab is to be used as monotherapy
<b>and</b>	
<input type="checkbox"/>	Treatment with methotrexate is contraindicated
<b>or</b>	
<input type="checkbox"/>	Patient has tried and did not tolerate oral and/or parenteral methotrexate
<b>and</b>	
<input type="checkbox"/>	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
<b>or</b>	
<input type="checkbox"/>	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
<b>and</b>	
<input type="checkbox"/>	Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints
<b>or</b>	
<input type="checkbox"/>	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
<b>and</b>	
<input type="checkbox"/>	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
<b>or</b>	
<input type="checkbox"/>	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

**Initial application — systemic juvenile idiopathic arthritis**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient diagnosed with systemic juvenile idiopathic arthritis
<b>and</b>	
<input type="checkbox"/>	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

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**Tocilizumab - continued**

**Initial application — adult-onset Still's disease**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

**Initial application — polyarticular juvenile idiopathic arthritis**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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 the above details are correct and that in signing this form I understand I may be audited.

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**Tocilizumab - continued**

**Initial application — idiopathic multicentric Castleman’s disease**

Applications only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Initial application — moderate to severe COVID-19**

Applications from any relevant practitioner. Approvals valid for 4 weeks.

**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 baricitinib

**Renewal — Rheumatoid Arthritis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

**Renewal — systemic juvenile idiopathic arthritis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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

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**Tocilizumab - continued**

**Renewal — adult-onset Still’s disease**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

- The patient has a sustained improvement in inflammatory markers and functional status

**Renewal — polyarticular juvenile idiopathic arthritis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
<b>and</b>	
<input type="checkbox"/>	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
<b>or</b>	
<input type="checkbox"/>	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

**Renewal — idiopathic multicentric Castleman’s disease**

Current approval Number (if known):.....

Applications only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

- The treatment remains appropriate and the patient has a sustained improvement in inflammatory markers and functional status

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**Trastuzumab emtansine**

**Initial application — early breast cancer**

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months.

**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 auxiliary 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)

**Initial application — metastatic breast cancer**

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 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 the above details are correct and that in signing this form I understand I may be audited.

Signed: ..... Date: .....  
Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Trastuzumab emtansine** - *continued*

**Renewal — metastatic breast cancer**

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<b>and</b>	<input type="checkbox"/> The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine
	<input type="checkbox"/> Treatment to be discontinued at disease progression

Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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## SA2233 - Rituximab

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**Rituximab** (Riximyo)

**Initial application — ABO-incompatible organ transplant**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

Patient is to undergo an ABO-incompatible solid organ transplant\*

Note: Indications marked with \* are unapproved indications.

**Initial application — ANCA associated vasculitis**

Applications from any relevant practitioner. Approvals valid for 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<sup>2</sup> 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.

**Renewal — ANCA associated vasculitis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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<sup>2</sup> of body-surface area per week for a total of 4 weeks

Note: Indications marked with \* are unapproved indications.

**Initial application — Antibody-mediated organ transplant rejection**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

Patient has been diagnosed with antibody-mediated organ transplant rejection\*

Note: Indications marked with \* are unapproved indications.

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**Rituximab** (Riximyo) - *continued*

**Initial application — Chronic lymphocytic leukaemia**

Applications from any relevant practitioner. Approvals valid for 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 within 36 months of previous treatment 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.

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**Rituximab** (Riximyo) - *continued*

**Renewal — Chronic lymphocytic leukaemia**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

The patient's disease has relapsed within 36 months of previous treatment 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 bendamustine

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.

**Initial application — Neuromyelitis Optica Spectrum Disorder(NMOSD)**

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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

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**Rituximab** (Riximyo) - *continued*

**Renewal — Neuromyelitis Optica Spectrum Disorder**

Current approval Number (if known):.....

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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/m<sup>2</sup> administered weekly for four weeks

**and**

The patient has responded to the most recent course of rituximab

**and**

The patient has not received rituximab in the previous 6 months

**Initial application — Post-transplant**

Applications from any relevant practitioner. Approvals valid for 12 months.

**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.

**Renewal — Post-transplant**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 9 months.

**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.

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**Rituximab** (Riximyo) - *continued*

**Initial application — Severe Refractory Myasthenia Gravis**

Applications only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

One of the following dose regimens is to be used: 375 mg/m<sup>2</sup> 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

**Renewal — Severe Refractory Myasthenia Gravis**

Current approval Number (if known):.....

Applications only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

One of the following dose regimens is to be used: 375 mg/m<sup>2</sup> 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

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**Rituximab** (Riximyo) - *continued*

**Initial application — Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)**

Applications only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks.

**Prerequisites**(tick boxes where appropriate)

- 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<sup>2</sup> of body surface area per week for a total of 4 weeks

Note: Indications marked with \* are unapproved indications.

**Renewal — Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)**

Current approval Number (if known):.....

Applications only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks.

**Prerequisites**(tick boxes where appropriate)

- 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<sup>2</sup> of body surface area per week for a total of 4 weeks

Note: Indications marked with \* are unapproved indications.

**Initial application — Steroid resistant nephrotic syndrome (SRNS)**

Applications only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks.

**Prerequisites**(tick boxes where appropriate)

- 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<sup>2</sup> of body surface area per week for a total of 4 weeks

Note: Indications marked with \* are unapproved indications.

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**Rituximab** (Riximyo) - *continued*

**Renewal — Steroid resistant nephrotic syndrome (SRNS)**

Current approval Number (if known):.....

Applications only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient who was previously treated with rituximab for nephrotic syndrome*
<b>and</b>	
<input type="checkbox"/>	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
<b>and</b>	
<input type="checkbox"/>	The total rituximab dose used would not exceed the equivalent of 375 mg/m <sup>2</sup> of body surface area per week for a total of 4 weeks

Note: Indications marked with \* are unapproved indications.

**Initial application — aggressive CD20 positive NHL**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has treatment naive aggressive CD20 positive NHL
<b>and</b>	
<input type="checkbox"/>	To be used with a multi-agent chemotherapy regimen given with curative intent
<b>and</b>	
<input type="checkbox"/>	To be used for a maximum of 8 treatment cycles
<b>or</b>	
<input type="checkbox"/>	The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy
<b>and</b>	
<input type="checkbox"/>	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

**Renewal — aggressive CD20 positive NHL**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has had a rituximab treatment-free interval of 12 months or more
<b>and</b>	
<input type="checkbox"/>	The patient has relapsed refractory/aggressive CD20 positive NHL
<b>and</b>	
<input type="checkbox"/>	To be used with a multi-agent chemotherapy regimen given with curative intent
<b>and</b>	
<input type="checkbox"/>	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

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**Rituximab** (Riximyo) - *continued*

**Initial application — haemophilia with inhibitors**

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has mild congenital haemophilia complicated by inhibitors <b>or</b> <input type="checkbox"/> Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy <b>or</b> <input type="checkbox"/> Patient has acquired haemophilia
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**Renewal — haemophilia with inhibitors**

Current approval Number (if known):.....

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient was previously treated with rituximab for haemophilia with inhibitors <b>and</b> <input type="checkbox"/> An initial response lasting at least 12 months was demonstrated <b>and</b> <input type="checkbox"/> Patient now requires repeat treatment
--

**Initial application — immune thrombocytopenic purpura (ITP)**

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microlitre <b>or</b> <input type="checkbox"/> Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding
<b>and</b>
<input type="checkbox"/> Treatment with steroids and splenectomy have been ineffective <b>or</b> <input type="checkbox"/> Treatment with steroids has been ineffective and splenectomy is an absolute contraindication <b>or</b> <input type="checkbox"/> Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy)
<b>and</b>
<input type="checkbox"/> The total rituximab dose used would not exceed the equivalent of 375 mg/m <sup>2</sup> of body surface area per week for a total of 4 weeks

Note: Indications marked with \* are unapproved indications.

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**Rituximab** (Riximyo) - *continued*

**Renewal — immune thrombocytopenic purpura (ITP)**

Current approval Number (if known):.....

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m <sup>2</sup> weekly for 4 weeks) is now planned
or
<input type="checkbox"/> Patient was previously treated with rituximab for immune thrombocytopenic purpura*
and
<input type="checkbox"/> An initial response lasting at least 12 months was demonstrated
and
<input type="checkbox"/> Patient now requires repeat treatment

Note: Indications marked with \* are unapproved indications.

**Initial application — indolent, low-grade lymphomas or hairy cell leukaemia\***

Applications from any relevant practitioner. Approvals valid for 9 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The patient has indolent low grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy
and
<input type="checkbox"/> To be used for a maximum of 6 treatment cycles
or
<input type="checkbox"/> The patient has indolent, low grade lymphoma or hairy cell leukaemia* requiring first-line systemic chemotherapy
and
<input type="checkbox"/> 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.

**Renewal — indolent, low-grade lymphomas or hairy cell leukaemia\***

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The patient has had a rituximab treatment-free interval of 12 months or more
and
<input type="checkbox"/> The patient has indolent, low-grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy
and
<input type="checkbox"/> 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.

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**Rituximab** (Riximyo) - *continued*

**Initial application — pure red cell aplasia (PRCA)**

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 weeks.

**Prerequisites**(tick box where appropriate)

Patient has autoimmune pure red cell aplasia\* associated with a demonstrable B-cell lymphoproliferative disorder

Note: Indications marked with \* are unapproved indications.

**Renewal — pure red cell aplasia (PRCA)**

Current approval Number (if known):.....

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 weeks.

**Prerequisites**(tick box where appropriate)

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.

**Initial application — severe cold haemagglutinin disease (CHAD)**

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.

**Prerequisites**(tick boxes where appropriate)

- 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/m<sup>2</sup> of body surface area per week for a total of 4 weeks

Note: Indications marked with \* are unapproved indications.

**Renewal — severe cold haemagglutinin disease (CHAD)**

Current approval Number (if known):.....

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.

**Prerequisites**(tick boxes where appropriate)

- Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m<sup>2</sup> 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.

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**Rituximab** (Riximyo) - *continued*

**Initial application — thrombotic thrombocytopenic purpura (TTP)**

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.

**Prerequisites**(tick boxes where appropriate)

The total rituximab dose used would not exceed the equivalent of 375 mg/m<sup>2</sup> 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.

**Renewal — thrombotic thrombocytopenic purpura (TTP)**

Current approval Number (if known):.....

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.

**Prerequisites**(tick boxes where appropriate)

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/m<sup>2</sup> of body surface area per week for a total of 4 weeks

Note: Indications marked with \* are unapproved indications.

**Initial application — treatment refractory systemic lupus erythematosus (SLE)**

Applications only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 7 months.

**Prerequisites**(tick boxes where appropriate)

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.

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**Rituximab** (Riximyo) - *continued*

**Renewal — treatment refractory systemic lupus erythematosus (SLE)**

Current approval Number (if known):.....

Applications only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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.

**Initial application — warm autoimmune haemolytic anaemia (warm AIHA)**

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.

**Prerequisites**(tick boxes where appropriate)

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/m<sup>2</sup> of body surface area per week for a total of 4 weeks

Note: Indications marked with \* are unapproved indications.

**Renewal — warm autoimmune haemolytic anaemia (warm AIHA)**

Current approval Number (if known):.....

Applications only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks.

**Prerequisites**(tick boxes where appropriate)

Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m<sup>2</sup> 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.

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**Rituximab** (Riximyo) - *continued*

**Initial application — severe antisynthetase syndrome**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has confirmed antisynthetase syndrome
<b>and</b>	
<input type="checkbox"/>	Patient has severe, immediately life or organ threatening disease, including interstitial lung disease
<b>and</b>	
<input type="checkbox"/>	Treatment with at least 3 immunosuppressants (oral steroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has not be effective at controlling active disease
<b>or</b>	
<input type="checkbox"/>	Rapid treatment is required due to life threatening complications
<b>and</b>	
<input type="checkbox"/>	Maximum of four 1,000mg infusions of rituximab

**Renewal — severe antisynthetase syndrome**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in inflammatory markers, muscle strength and pulmonary function
<b>and</b>	
<input type="checkbox"/>	The patient has not received rituximab in the previous 6 months
<b>and</b>	
<input type="checkbox"/>	Maximum of two cycles of 2 × 1,000mg infusions of rituximab given two weeks apart

**Initial application — graft versus host disease**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has refractory graft versus host disease following transplant
<b>and</b>	
<input type="checkbox"/>	Treatment with at least 3 immunosuppressants (oral steroids, ciclosporin, tacrolimus, mycophenolate, sirolimus) has not be effective at controlling active disease
<b>and</b>	
<input type="checkbox"/>	The total rituximab dose used would not exceed the equivalent of 375 mg/m <sup>2</sup> of body surface area per week for a total of 4 weeks

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**Rituximab** (Riximyo) - *continued*

**Initial application — severe chronic inflammatory demyelinating polyneuropathy**

Applications only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has severe chronic inflammatory demyelinating polyneuropathy (CIPD)			
<b>and</b>			
<table border="1"> <tr> <td><input type="checkbox"/> Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease</td> </tr> <tr> <td><b>and</b></td> </tr> <tr> <td><input type="checkbox"/> At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease</td> </tr> </table>	<input type="checkbox"/> Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease	<b>and</b>	<input type="checkbox"/> At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease
<input type="checkbox"/> Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease			
<b>and</b>			
<input type="checkbox"/> At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease			
<b>or</b>			
<input type="checkbox"/> Rapid treatment is required due to life threatening complications			
<b>and</b>			
<input type="checkbox"/> One of the following dose regimens is to be used: 375 mg/m <sup>2</sup> 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			

**Renewal — severe chronic inflammatory demyelinating polyneuropathy**

Current approval Number (if known):.....

Applications only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function compared to baseline
<b>and</b>
<input type="checkbox"/> The patient has not received rituximab in the previous 6 months
<b>and</b>
<input type="checkbox"/> One of the following dose regimens is to be used: 375 mg/m <sup>2</sup> 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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**Rituximab** (Riximyo) - *continued*

**Initial application — anti-NMDA receptor autoimmune encephalitis**

Applications only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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/m<sup>2</sup> 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

**Renewal — anti-NMDA receptor autoimmune encephalitis**

Current approval Number (if known):.....

Applications only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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/m<sup>2</sup> 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

**Initial application — CD20+ low grade or follicular B-cell NHL**

Applications from any relevant practitioner. Approvals valid for 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

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**Rituximab** (Riximyo) - *continued*

**Renewal — CD20+ low grade or follicular B-cell NHL**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 24 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Rituximab is to be used for maintenance in CD20+ low grade or follicular B-cell NHL following induction with first-line systemic chemotherapy
<b>and</b>	
<input type="checkbox"/>	Patient is intended to receive rituximab maintenance therapy for 2 years at a dose of 375 mg/m <sup>2</sup> every 8 weeks (maximum of 12 cycles)

**Initial application — Membranous nephropathy**

Applications only from a nephrologist or any relevant practitioner on the recommendation of a nephrologist. Approvals valid for 6 weeks.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has biopsy-proven primary/idiopathic membranous nephropathy*
<b>or</b>	
<input type="checkbox"/>	Patient has PLA2 antibodies with no evidence of secondary cause, and an eGFR of > 60ml/min/1.73m <sup>2</sup>
<b>and</b>	
<input type="checkbox"/>	Patient remains at high risk of progression to end-stage kidney disease despite more than 3 months of treatment with conservative measures (see Note)
<b>and</b>	
<input type="checkbox"/>	The total rituximab dose would not exceed the equivalent of 375mg/m <sup>2</sup> of body surface area per week for a total of 4 weeks

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**Rituximab** (Riximyo) - *continued*

**Renewal — Membranous nephropathy**

Current approval Number (if known):.....

Applications only from a nephrologist or any relevant practitioner on the recommendation of a nephrologist. Approvals valid for 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/m<sup>2</sup> 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.

**Initial application — B-cell acute lymphoblastic leukaemia/lymphoma\***

Applications only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 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/m<sup>2</sup> per dose for a maximum of 18 doses

Note: Indications marked with \* are unapproved indications.

**Initial application — desensitisation prior to transplant**

Applications from any relevant practitioner. Approvals valid for 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/m<sup>2</sup> of body-surface area

Note: Indications marked with \* are unapproved indications.

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**Rituximab** (Riximyo) - *continued*

**Initial application — pemphigus\***

Applications only from a dermatologist or relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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.

**Renewal — pemphigus\***

Current approval Number (if known):.....

Applications only from a dermatologist or relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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.

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**Rituximab** (Riximyo) - *continued*

**Initial application — immunoglobulin G4-related disease (IgG4-RD\*)**

Applications from any relevant practitioner. Approvals valid for 6 weeks.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has confirmed diagnosis of IgG4-RD*
<b>and</b>	
<input type="checkbox"/>	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
<b>or</b>	
<input type="checkbox"/>	Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs is contraindicated or associated with evidence of toxicity or intolerance
<b>and</b>	
<input type="checkbox"/>	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.

**Renewal — immunoglobulin G4-related disease (IgG4-RD\*)**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Treatment with rituximab for IgG4-RD* was previously successful and patient's disease has demonstrated sustained response, but the condition has relapsed
<b>or</b>	
<input type="checkbox"/>	Patient is receiving maintenance treatment for IgG4-RD*
<b>and</b>	
<input type="checkbox"/>	Rituximab re-treatment not to be given within 6 months of previous course of treatment
<b>and</b>	
<input type="checkbox"/>	Maximum of two 1000 mg infusions of rituximab given two weeks apart

Note: Indications marked with \* are unapproved indications.

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**Mepolizumab**

**Initial application — Severe eosinophilic asthma**

Applications only from a respiratory physician or clinical immunologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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  $0.5 \times 10^9$  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

**Renewal — Severe eosinophilic asthma**

Current approval Number (if known):.....

Applications only from a respiratory physician or clinical immunologist. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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

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**Mepolizumab** - *continued*

**Initial application — eosinophilic granulomatosis with polyangiitis**

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has eosinophilic granulomatosis with polyangiitis
<b>and</b>	
<input type="checkbox"/>	The patient has trialed 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
<b>and</b>	
<input type="checkbox"/>	The patient has trialed prednisone for a minimum of three months and is unable to maintain disease control at doses below 7.5 mg per day
<b>or</b>	
<input type="checkbox"/>	Corticosteroids are contraindicated

**Renewal — eosinophilic granulomatosis with polyangiitis**

Current approval Number (if known):.....

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

Patient has no evidence of clinical disease progression

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**Casirivimab and imdevimab**

**Initial application — Treatment of profoundly immunocompromised patients**

Applications from any relevant practitioner. Approvals valid for 2 weeks.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has confirmed (or probable) COVID-19
<b>and</b>	
<input type="checkbox"/>	The patient is in the community with mild to moderate disease severity*
<b>and</b>	
<input type="checkbox"/>	Patient is profoundly immunocompromised** and is at risk of not having mounted an adequate response to vaccination against COVID-19 or is unvaccinated
<b>and</b>	
<input type="checkbox"/>	Patient's symptoms started within the last 10 days
<b>and</b>	
<input type="checkbox"/>	Patient is not receiving high flow oxygen or assisted/mechanical ventilation
<b>and</b>	
<input type="checkbox"/>	Casirivimab and imdevimab is to be administered at a maximum dose of no greater than 2,400 mg

Note: \* Mild to moderate disease severity as described on the [Ministry of Health Website](#)

\*\* Examples include B-cell depletive illnesses or patients receiving treatment that is B-Cell depleting.

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## SA2400 - Adalimumab (Amgevita)

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**Adalimumab (Amgevita)**

**Initial application — Behcet’s disease - severe**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has severe Behcet’s disease* that is significantly impacting the patient’s quality of life
<b>and</b>	
<input type="checkbox"/>	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)
<b>or</b>	
<input type="checkbox"/>	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.

**Initial application — Hidradenitis suppurativa**

Applications only from a dermatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas
<b>and</b>	
<input type="checkbox"/>	Patient has tried, but had an inadequate response to at least a 90 day trial of systemic antibiotics or has demonstrated intolerance to or has contraindications for systemic antibiotics
<b>and</b>	
<input type="checkbox"/>	Patient has 3 or more active lesions
<b>and</b>	
<input type="checkbox"/>	The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application

**Renewal — Hidradenitis suppurativa**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline
<b>and</b>	
<input type="checkbox"/>	The patient has a DLQI improvement of 4 or more from baseline

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**Adalimumab (Amgevita) - continued**

**Initial application — Plaque psoriasis - severe chronic**

Applications only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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 the above details are correct and that in signing this form I understand I may be audited.**

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**Adalimumab (Amgevita) - continued**

**Renewal — Plaque psoriasis - severe chronic**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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 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 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

**Initial application — pyoderma gangrenosum**

Applications only from a dermatologist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

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 has not received an adequate response

Note: Indications marked with \* are unapproved indications.

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**Adalimumab (Amgevita) - continued**

**Initial application — Crohn's disease - adults**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal — Crohn's disease - adults**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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 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

**Initial application — Crohn's disease - children**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

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**Adalimumab (Amgevita) - continued**

**Renewal — Crohn’s disease - children**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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

**Initial application — Crohn’s disease - fistulising**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal — Crohn’s disease - fistulising**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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

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**Adalimumab (Amgevita) - continued**

**Initial application — Ocular inflammation - chronic**

Applications from any relevant practitioner. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal — Ocular inflammation - chronic**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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

**Initial application — Ocular inflammation - severe**

Applications from any relevant practitioner. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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

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**Adalimumab (Amgevita) - continued**

**Renewal — Ocular inflammation - severe**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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

**Initial application — ankylosing spondylitis**

Applications only from a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis

and

The patient has experienced intolerable side effects

or

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

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)

or

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

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**Adalimumab (Amgevita) - continued**

**Renewal — ankylosing spondylitis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

- 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

**Initial application — Arthritis - oligoarticular course juvenile idiopathic**

Applications only from a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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)

**Renewal — Arthritis - oligoarticular course juvenile idiopathic**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

- 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

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**Adalimumab (Amgevita) - continued**

**Initial application — Arthritis - polyarticular course juvenile idiopathic**

Applications only from a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal — Arthritis - polyarticular course juvenile idiopathic**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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

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**Adalimumab (Amgevita) - continued**

**Initial application — Arthritis - psoriatic**

Applications only from a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis <b>and</b> <input type="checkbox"/> The patient has experienced intolerable side effects <b>or</b> <input type="checkbox"/> The patient has received insufficient benefit from to meet the renewal criteria for psoriatic arthritis
<b>or</b>
<input type="checkbox"/> Patient has had active psoriatic arthritis for six months duration or longer <b>and</b> <input type="checkbox"/> Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated) <b>and</b> <input type="checkbox"/> Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated) <b>and</b> <input type="checkbox"/> Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints <b>or</b> <input type="checkbox"/> 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 <b>and</b> <input type="checkbox"/> Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application <b>or</b> <input type="checkbox"/> Patient has an ESR greater than 25 mm per hour <b>or</b> <input type="checkbox"/> 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

**Renewal — Arthritis - psoriatic**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> 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 <b>or</b> <input type="checkbox"/> 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
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**Adalimumab (Amgevita) - continued**

**Initial application — Arthritis - rheumatoid**

Applications only from a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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 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

**Renewal — Arthritis - rheumatoid**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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

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**Adalimumab (Amgevita) - continued**

**Initial application — Still's disease - adult-onset (AOSD)**

Applications only from a rheumatologist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for AOSD

**and**

Patient has experienced intolerable side effects from etanercept and/or tocilizumab

**or**

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

**Initial application — ulcerative colitis**

Applications from any relevant practitioner. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

Patient has active ulcerative colitis

**and**

Patient's 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 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

**Renewal — ulcerative colitis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on biologic therapy

**or**

The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiation on biologic therapy

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**Adalimumab (Amgevita) - continued**

**Initial application — undifferentiated spondyloarthritis**

Applications only from a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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, sulfasalazine 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

**Renewal — undifferentiated spondyloarthritis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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

**Initial application — inflammatory bowel arthritis – axial**

Applications only from a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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

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**Adalimumab (Amgevita) - continued**

**Renewal — inflammatory bowel arthritis – axial**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

- 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

**Initial application — inflammatory bowel arthritis – peripheral**

Applications only from a rheumatologist. Approvals valid for 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

**Renewal — inflammatory bowel arthritis – peripheral**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

- Following initial treatment, 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 has experienced at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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**Palivizumab**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Palivizumab to be administered during the annual RSV season
<b>and</b>	
<input type="checkbox"/>	Infant was born in the last 12 months
<b>and</b>	
<input type="checkbox"/>	Infant was born at less than 32 weeks zero days' gestation
<b>or</b>	
<input type="checkbox"/>	Child was born in the last 24 months
<b>and</b>	
<input type="checkbox"/>	Child has severe lung, airway, neurological or neuromuscular disease that requires ongoing ventilatory/respiratory support (see Note A) in the community
<b>or</b>	
<input type="checkbox"/>	Child has haemodynamically significant heart disease
<b>and</b>	
<input type="checkbox"/>	Child has unoperated simple congenital heart disease with significant left to right shunt (see Note B)
<b>or</b>	
<input type="checkbox"/>	Child has unoperated or surgically palliated complex congenital heart disease
<b>or</b>	
<input type="checkbox"/>	Child has severe pulmonary hypertension (see Note C)
<b>or</b>	
<input type="checkbox"/>	Child has moderate or severe left ventricular (LV) failure (see Note D)
<b>or</b>	
<input type="checkbox"/>	Child has severe combined immune deficiency, confirmed by an immunologist, but has not received a stem cell transplant
<b>or</b>	
<input type="checkbox"/>	Child has inborn errors of immunity (see Note E) that increase susceptibility to life-threatening viral respiratory infections, confirmed by an immunologist

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**Palivizumab** - continued

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

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**Gemtuzumab ozogamicin**

**Initial application**

Applications only from a haematologist, paediatric haematologist or paediatric oncologist. Approvals valid for 3 months.

**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<sup>2</sup> 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).

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**Benralizumab**

**Initial application — Severe eosinophilic asthma**

Applications only from a respiratory physician or clinical immunologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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  $0.5 \times 10^9$  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

**Renewal — Severe eosinophilic asthma**

Current approval Number (if known):.....

Applications only from a respiratory physician or clinical immunologist. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

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

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**Ustekinumab**

**Initial application — Crohn's disease - adults**  
Applications from any relevant practitioner. Approvals valid for 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

**Renewal — Crohn's disease - adults**  
Current approval Number (if known):.....  
Applications from any relevant practitioner. Approvals valid for 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

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Ustekinumab** - *continued*

**Initial application — Crohn's disease - children\***

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	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
<b>or</b>	
<input type="checkbox"/>	Patient has active Crohn's disease
<b>and</b>	
<input type="checkbox"/>	Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria
<b>or</b>	
<input type="checkbox"/>	Patient meets the initiation criteria for prior biologic therapies for Crohn's disease
<b>and</b>	
<input type="checkbox"/>	Other biologics for Crohn's disease are contraindicated

Note: Indication marked with \* is an unapproved indication.

**Renewal — Crohn's disease - children\***

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy
<b>or</b>	
<input type="checkbox"/>	PCDAI score is 15 or less
<b>or</b>	
<input type="checkbox"/>	The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed
<b>and</b>	
<input type="checkbox"/>	Ustekinumab to administered at a dose no greater than 90 mg every 8 weeks

Note: Indication marked with \* is an unapproved indication.

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**Ustekinumab - continued**

**Initial application — ulcerative colitis**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	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
<b>or</b>	
<input type="checkbox"/>	Patient has active ulcerative colitis
<b>and</b>	
<input type="checkbox"/>	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
<b>or</b>	
<input type="checkbox"/>	Patient meets the initiation criteria for prior biologic therapies for ulcerative colitis
<b>and</b>	
<input type="checkbox"/>	Other biologics for ulcerative colitis are contraindicated

**Renewal — ulcerative colitis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy
<b>or</b>	
<input type="checkbox"/>	PUCAI score has reduced by 10 points or more from the PUCAI score since initiation on biologic therapy*
<b>and</b>	
<input type="checkbox"/>	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.

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**Vedolizumab**

**Initial application — Crohn’s disease - adults**  
Applications from any relevant practitioner. Approvals valid for 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

**Renewal — Crohn’s disease - adults**  
Current approval Number (if known):.....  
Applications from any relevant practitioner. Approvals valid for 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 the above details are correct and that in signing this form I understand I may be audited.

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**Vedolizumab - continued**

**Initial application — Crohn’s disease - children\***

Applications from any relevant practitioner. Approvals valid for 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.

**Renewal — Crohn’s disease - children\***

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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.

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**Vedolizumab - continued**

**Initial application — ulcerative colitis**

Applications from any relevant practitioner. Approvals valid for 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.

**Renewal — ulcerative colitis**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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.

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**Brentuximab**

**Initial application — relapsed/refractory Hodgkin lymphoma**

Applications from any relevant practitioner. Approvals valid for 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

**Renewal — relapsed/refractory Hodgkin lymphoma**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

**Initial application — anaplastic large cell lymphoma**

Applications from any relevant practitioner. Approvals valid for 6 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

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**Brentuximab** - *continued*

**Renewal — anaplastic large cell lymphoma**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

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**Trastuzumab (Herzuma)**

**Initial application — early breast cancer**

Applications from any relevant practitioner. Approvals valid for 15 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)

**Renewal — early breast cancer\***

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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**

The 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 the above details are correct and that in signing this form I understand I may be audited.**

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

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**Trastuzumab (Herzuma) - continued**

**Initial application — metastatic breast cancer**

Applications from any relevant practitioner. Approvals valid for 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

**Renewal — metastatic breast cancer**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

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**Trastuzumab (Herzuma) - continued**

**Initial application — gastric, gastro-oesophageal junction and oesophageal cancer**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> 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) <b>and</b> <input type="checkbox"/> Patient has an ECOG score of 0-2
--

**Renewal — gastric, gastro-oesophageal junction and oesophageal cancer**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab <b>and</b> <input type="checkbox"/> Trastuzumab to be discontinued at disease progression
--

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**Trastuzumab deruxtecan**

**Initial application**

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

Patient is currently on treatment with trastuzumab deruxtecan and met all remaining criteria prior to commencing treatment

or

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

**Renewal**

Current approval Number (if known):.....

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 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.

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**Nivolumab**

**Initial application**

Applications only from a medical oncologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

Patient 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 patient has ECOG performance score of 0-2

and

Patient has not received funded pembrolizumab

or

Patient 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 patient was on pembrolizumab

and  Documentation confirming that the patient has been informed and acknowledges that funded treatment with nivolumab will not be continued if their disease progresses

**Renewal — less than 24 months on treatment**

Current approval Number (if known):.....

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 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  Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

and  The treatment remains clinically appropriate and the patient is benefitting from the treatment

or

Patient has previously discontinued treatment with nivolumab 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 nivolumab

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

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**Nivolumab - continued**

**Renewal — more than 24 months on treatment**

Current approval Number (if known):.....

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

Patient has been on treatment for more than 24 months

**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 or clinical assessment following the most recent treatment period

**and**

The treatment remains clinically appropriate and the patient is benefitting from the treatment

**or**

Patient has previously discontinued treatment with nivolumab 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 nivolumab

**Initial application — Renal cell carcinoma**

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

Patient is currently on treatment with nivolumab and met all remaining criteria prior to commencing treatment

**or**

Patient has metastatic renal-cell carcinoma

**and**

The disease is of predominant clear-cell histology

**and**

Patient has an ECOG performance score of 0-2

**and**

Patient has documented disease progression following one or two previous regimens of antiangiogenic therapy

**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 the above details are correct and that in signing this form I understand I may be audited.**

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

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**Nivolumab** - *continued*

**Renewal — Renal cell carcinoma**

Current approval Number (if known):.....

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 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 the above details are correct and that in signing this form I understand I may be audited.

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## SA2386 - Pembrolizumab

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**Pembrolizumab**

**Initial application — unresectable or metastatic melanoma**

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

Patient 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 patient has ECOG performance score of 0-2

and

Patient has not received funded nivolumab

or

Patient 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 patient was on nivolumab

and  Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses

**Renewal — unresectable or metastatic melanoma, less than 24 months on treatment**

Current approval Number (if known):.....

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 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  Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

and  The treatment remains clinically appropriate and the patient is benefitting from the treatment

or

Patient has previously discontinued treatment with pembrolizumab 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 pembrolizumab

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Pembrolizumab - continued**

**Renewal — unresectable or metastatic melanoma, more than 24 months on treatment**

Current approval Number (if known):.....

Applications only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

Patient has been on treatment for more than 24 months

**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 or clinical assessment following the most recent treatment period

**and**

The treatment remains clinically appropriate and the patient is benefitting from the treatment

**or**

Patient has previously discontinued treatment with pembrolizumab 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 pembrolizumab

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**Pembrolizumab - continued**

**Initial application — non-small cell lung cancer first-line monotherapy**

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

- 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 the above details are correct and that in signing this form I understand I may be audited.

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

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**Pembrolizumab - continued**

**Renewal — non-small cell lung cancer first line monotherapy**

Current approval Number (if known):.....

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 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  
 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)

**Initial application — non-small cell lung cancer first-line combination therapy**

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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 the above details are correct and that in signing this form I understand I may be audited.**

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**Pembrolizumab - continued**

**Renewal — non-small cell lung cancer first line combination therapy**

Current approval Number (if known):.....

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 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

- 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)

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Pembrolizumab - continued**

**Initial application — breast cancer, advanced**

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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 the above details are correct and that in signing this form I understand I may be audited.

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**Pembrolizumab - continued**

**Renewal — breast cancer, advanced**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 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  
 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)

**Initial application — head and neck squamous cell carcinoma**

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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 the above details are correct and that in signing this form I understand I may be audited.

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

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**Pembrolizumab - continued**

**Renewal — head and neck squamous cell carcinoma**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient's disease has had a complete response to treatment <b>or</b> <input type="checkbox"/> Patient's disease has had a partial response to treatment <b>or</b> <input type="checkbox"/> Patient has stable disease
<b>and</b>
<input type="checkbox"/> No evidence of disease progression
<b>and</b>
<input type="checkbox"/> Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent)
<b>and</b>
<input type="checkbox"/> Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

**Initial application — MSI-H/dMMR advanced colorectal cancer**

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment <b>or</b>
<input type="checkbox"/> Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer <b>or</b> <input type="checkbox"/> Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer
<b>and</b>
<input type="checkbox"/> Patient is treated with palliative intent
<b>and</b>
<input type="checkbox"/> Patient has not previously received funded treatment with pembrolizumab
<b>and</b>
<input type="checkbox"/> Patient has an ECOG performance score of 0-2
<b>and</b>
<input type="checkbox"/> Baseline measurement of overall tumour burden is documented clinically and radiologically
<b>and</b>
<input type="checkbox"/> Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Pembrolizumab - continued**

**Renewal — MSI-H/dMMR advanced colorectal cancer**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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)

**Initial application — Urothelial carcinoma**

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal — Urothelial carcinoma**

Current approval Number (if known):.....

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 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  
 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)

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**Pembrolizumab - continued**

**Initial application — relapsed/refractory Hodgkin lymphoma**

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment
<b>or</b>	
<input type="checkbox"/>	Patient has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy
<b>and</b>	
<input type="checkbox"/>	Patient is ineligible for autologous stem cell transplant
<b>or</b>	
<input type="checkbox"/>	Patient has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant
<b>and</b>	
<input type="checkbox"/>	Patient has not previously received funded pembrolizumab
<b>and</b>	
<input type="checkbox"/>	Pembrolizumab to be administered at doses no greater than 200 mg once every 3 weeks

**Renewal — relapsed/refractory Hodgkin lymphoma**

Current approval Number (if known):.....

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has received a partial or complete response to pembrolizumab
<b>and</b>	
<input type="checkbox"/>	Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

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**Durvalumab**

**Initial application — Non-small cell lung cancer**

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 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

or

Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks

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

**Renewal — Non-small cell lung cancer**

Current approval Number (if known):.....

Applications only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

The treatment remains clinically appropriate and the patient is benefitting from treatment

and

or

Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks

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

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**Atezolizumab**

**Initial application — non-small cell lung cancer second line monotherapy**

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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

**Renewal — non-small cell lung cancer second line monotherapy**

Current approval Number (if known):.....

Applications only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 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**

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)

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**Tacrolimus**

**Initial application — organ transplant**

Applications only from a relevant specialist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The patient is an organ transplant recipient

Note: Subsidy applies for either primary or rescue therapy.

**Initial application — non-transplant indications\***

Applications only from a relevant specialist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient requires long-term systemic immunosuppression
<b>and</b>
<input type="checkbox"/> Ciclosporin has been trialled and discontinued treatment because of unacceptable side effects or inadequate clinical response
<b>or</b>
<input type="checkbox"/> Patient is a child with nephrotic syndrome*

Note: Indications marked with \* are unapproved indications

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**Sirolimus (Rapamune)**

**Initial application**

Applications from any medical practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The drug is to be used 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
- Leukoencephalopathy; or
- Significant malignant disease

**Initial application — severe non-malignant lymphovascular malformations\***

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has severe non-malignant lymphovascular malformation*
<b>and</b>	
<input type="checkbox"/>	Malformations are not adequately controlled by sclerotherapy and surgery
<b>or</b>	
<input type="checkbox"/>	Malformations are widespread/extensive and sclerotherapy and surgery are not considered clinically appropriate
<b>or</b>	
<input type="checkbox"/>	Sirolimus is to be used to reduce malformation prior to consideration of surgery
<b>and</b>	
<input type="checkbox"/>	Patient is being treated by a specialist lymphovascular malformation multi-disciplinary team
<b>and</b>	
<input type="checkbox"/>	Patient has measurable disease as defined by RECIST version 1.1 (see Note)

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**Sirolimus (Rapamune) - continued**

**Renewal — severe non-malignant lymphovascular malformations\***

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

**Initial application — renal angiomyolipoma(s) associated with tuberous sclerosis complex\***

Applications only from a nephrologist or urologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

Patient has tuberous sclerosis complex\*

and

Evidence of renal angiomyolipoma(s) measuring 3 cm or greater and that have shown interval growth

**Renewal — renal angiomyolipoma(s) associated with tuberous sclerosis complex\***

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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

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**Sirolimus (Rapamune) - continued**

**Initial application — refractory seizures associated with tuberous sclerosis complex\***

Applications only from a neurologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

Patient has epilepsy with a background of documented tuberous sclerosis complex

**and**

Vigabatrin has been trialed 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 age potential are not required to trial phenytoin sodium, sodium valproate, or topiramate. Those who can father children are not required to trial sodium valproate.

**Renewal — refractory seizures associated with tuberous sclerosis complex\***

Current approval Number (if known):.....

Applications only from a neurologist. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

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

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**Everolimus**

**Initial application**

Applications only from a neurologist or oncologist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

Patient has tuberous sclerosis  
and  
 Patient has progressively enlarging sub-ependymal giant cell astrocytomas (SEGAs) that require treatment

**Renewal**

Current approval Number (if known):.....

Applications only from a neurologist or oncologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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

**Initial application — renal cell carcinoma**

Applications from any relevant practitioner. Approvals valid for 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

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**Everolimus** - *continued*

**Renewal — renal cell carcinoma**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 4 months.

**Prerequisites**(tick box where appropriate)

There is no evidence of disease progression

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**Upadacitinib**

**Initial application — Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)**  
Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.  
**Prerequisites**(tick boxes where appropriate)

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

**Renewal — Rheumatoid Arthritis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.  
**Prerequisites**(tick boxes where appropriate)

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

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**Respiratory System and Allergies**

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**Adrenaline**

**Initial application — anaphylaxis**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

- Patient has experienced an 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

- and**
- Patient is not to be prescribed more than two devices in initial prescription

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**Icatibant**

**Initial application**

Applications only from a clinical immunologist or relevant specialist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	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
<b>and</b>	
<input type="checkbox"/>	The patient has undergone product training and has agreed upon an action plan for self-administration

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

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<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT NHI:</b> .....	<b>REFERRER</b> Reg No: .....
Reg No: .....	First Names: .....	First Names: .....
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Address: .....	DOB: .....	Address: .....
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**Bee or wasp venom allergy treatment**

**Initial application**  
Applications only from a relevant specialist. Approvals valid for 2 years.  
**Prerequisites**(tick boxes where appropriate)

<b>and</b>	<input type="checkbox"/> RAST or skin test positive  <input type="checkbox"/> Patient has had severe generalised reaction to the sensitising agent
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**Renewal**  
Current approval Number (if known):.....  
Applications only from a relevant specialist. Approvals valid for 2 years.  
**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

I confirm the above details are correct and that in signing this form I understand I may be audited.

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Fax Number: .....      Fax Number: .....

**Long-Acting Muscarinic Antagonists with Long-Acting Beta-Adrenoceptor Agonists**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 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

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 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 the above details are correct and that in signing this form I understand I may be audited.

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Fax Number: .....      Fax Number: .....

**Fluticasone furoate with umeclidinium and vilanterol**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Patient has a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible
<b>and</b>
<input type="checkbox"/> 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)
<b>and</b>
<b>Clinical criteria:</b>
<input type="checkbox"/> Patient has a COPD Assessment Test (CAT) score greater than 10
<b>or</b>
<input type="checkbox"/> Patient has had 2 or more exacerbations in the previous 12 months
<b>or</b>
<input type="checkbox"/> Patient has had one exacerbation requiring hospitalisation in the previous 12 months
<b>or</b>
<input type="checkbox"/> Patient has had an eosinophil count greater than or equal to $0.3 \times 10^9$ cells/L in the previous 12 months
<b>or</b>
<input type="checkbox"/> 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 the above details are correct and that in signing this form I understand I may be audited.

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**Budesonide with glycopyrronium and eformoterol**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**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  $0.3 \times 10^9$  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

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**Pirfenidone**

**Initial application — idiopathic pulmonary fibrosis**

Applications only from a respiratory specialist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist
and	
<input type="checkbox"/>	Forced vital capacity is between 50% and 90% predicted
and	
<input type="checkbox"/>	Pirfenidone is to be discontinued at disease progression (See Note)
and	
<input type="checkbox"/>	Pirfenidone is not to be used in combination with subsidised nintedanib
and	
<input type="checkbox"/>	The patient has not previously received treatment with nintedanib
or	
<input type="checkbox"/>	Patient has previously received nintedanib, but discontinued nintedanib within 12 weeks due to intolerance
or	
<input type="checkbox"/>	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)

**Renewal — idiopathic pulmonary fibrosis**

Current approval Number (if known):.....

Applications only from a respiratory specialist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment
and	
<input type="checkbox"/>	Pirfenidone is not to be used in combination with subsidised nintedanib
and	
<input type="checkbox"/>	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.

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

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**Nintedanib**

**Initial application — idiopathic pulmonary fibrosis**

Applications only from a respiratory specialist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist
and	
<input type="checkbox"/>	Forced vital capacity is between 50% and 90% predicted
and	
<input type="checkbox"/>	Nintedanib is to be discontinued at disease progression (See Note)
and	
<input type="checkbox"/>	Nintedanib is not to be used in combination with subsidised pirfenidone
and	
<input type="checkbox"/>	The patient has not previously received treatment with pirfenidone
or	
<input type="checkbox"/>	Patient has previously received pirfenidone, but discontinued pirfenidone within 12 weeks due to intolerance
or	
<input type="checkbox"/>	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)

**Renewal — idiopathic pulmonary fibrosis**

Current approval Number (if known):.....

Applications only from a respiratory specialist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment
and	
<input type="checkbox"/>	Nintedanib is not to be used in combination with subsidised pirfenidone
and	
<input type="checkbox"/>	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.

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**Dornase Alfa**

**Initial application — cystic fibrosis**

Applications only from a respiratory physician or paediatrician. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has a confirmed diagnosis of cystic fibrosis
<b>and</b>	
<input type="checkbox"/>	Patient has previously undergone a trial with, or is currently being treated with, hypertonic saline
<b>and</b>	
<input type="checkbox"/>	Patient has required one or more hospital inpatient respiratory admissions in the previous 12 month period
<b>or</b>	
<input type="checkbox"/>	Patient has had 3 exacerbations due to CF, requiring oral or intravenous (IV) antibiotics in the previous 12 month period
<b>or</b>	
<input type="checkbox"/>	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
<b>or</b>	
<input type="checkbox"/>	Patient has a diagnosis of allergic bronchopulmonary aspergillosis (ABPA)

**Renewal — cystic fibrosis**

Current approval Number (if known):.....

Applications only from a respiratory physician or paediatrician. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient continues to benefit from treatment

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**Ivacaftor**

**Initial application**

Applications only from a respiratory specialist or paediatrician. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

- 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 the above details are correct and that in signing this form I understand I may be audited.

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

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**Elexacaftor with tezacaftor, ivacaftor and ivacaftor**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient has been diagnosed with cystic fibrosis
<b>and</b>	
<input type="checkbox"/>	Patient is 6 years of age or older
<b>and</b>	
<input type="checkbox"/>	Patient has two cystic fibrosis-causing mutations in the cystic fibrosis transmembrane regulator (CFTR) gene (one from each parental allele)
<b>or</b>	
<input type="checkbox"/>	Patient has a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system
<b>and</b>	
<input type="checkbox"/>	Patient has a heterozygous or homozygous F508del mutation
<b>or</b>	
<input type="checkbox"/>	Patient has a G551D mutation or other mutation responsive in vitro to elexacaftor/tezacaftor/ivacaftor (see note a)
<b>and</b>	
<input type="checkbox"/>	The treatment must be the sole funded CFTR modulator therapy for this condition
<b>and</b>	
<input type="checkbox"/>	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://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212273s004lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212273s004lbl.pdf)

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## Sensory Organs



**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER** Reg No: .....

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Address: .....      DOB: .....      Address: .....

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**Dexamethasone 700 mcg ocular implants**

**Initial application — Diabetic macular oedema**

Applications only from an ophthalmologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

Patient has 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

**Renewal — Diabetic macular oedema**

Current approval Number (if known):.....

Applications only from an ophthalmologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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

**Initial application — Women of child bearing age with diabetic macular oedema**

Applications only from an ophthalmologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

Patient has 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 the above details are correct and that in signing this form I understand I may be audited.**

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**Dexamethasone 700 mcg ocular implants** - *continued*

**Renewal — Women of child bearing age with diabetic macular oedema**

Current approval Number (if known):.....

Applications only from an ophthalmologist. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient's vision is stable or has improved (prescriber determined)
<b>and</b>	
<input type="checkbox"/>	Patient is of child bearing potential and has not yet completed a family
<b>and</b>	
<input type="checkbox"/>	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 the above details are correct and that in signing this form I understand I may be audited.**

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**Prednisolone sodium phosphate**

**Initial application**

Applications only from an ophthalmologist or optometrist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<b>and</b>	<input type="checkbox"/> Patient has severe inflammation
	<input type="checkbox"/> Patient has a confirmed allergic reaction to preservative in eye drops

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

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**Pilocarpine – Eye drops 2% single dose**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<b>or</b>	<input type="checkbox"/> Patient has to use an unpreserved solution due to an allergy to the preservative
	<input type="checkbox"/> Patient wears soft contact lenses

Note: Minims for a general practice are considered to be “tools of trade” and are not approved as special authority items.

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

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**Preservative Free Ocular Lubricants**

**Initial application**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Confirmed diagnosis by slit lamp or Schirmer test of severe secretory dry eye <b>and</b> <input type="checkbox"/> Patient is using eye drops more than four times daily on a regular basis <b>or</b> <input type="checkbox"/> Patient has had a confirmed allergic reaction to preservative in eye drop
--

**Renewal**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 24 months.

**Prerequisites**(tick box where appropriate)

The patient continues to require lubricating eye drops and has benefited from treatment

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

**Various**

<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT NHI:</b> .....	<b>REFERRER</b> Reg No: .....
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**Deferiprone**

<p><b>Initial application</b> Applications only from a haematologist. Approvals valid without further renewal unless notified.</p> <p><b>Prerequisites</b>(tick boxes where appropriate)</p> <table border="1"><tr><td><input type="checkbox"/></td><td>The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia</td></tr><tr><td><b>or</b></td><td></td></tr><tr><td><input type="checkbox"/></td><td>The patient has been diagnosed with chronic iron overload due to acquired red cell aplasia</td></tr></table>	<input type="checkbox"/>	The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia	<b>or</b>		<input type="checkbox"/>	The patient has been diagnosed with chronic iron overload due to acquired red cell aplasia
<input type="checkbox"/>	The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia					
<b>or</b>						
<input type="checkbox"/>	The patient has been diagnosed with chronic iron overload due to acquired red cell aplasia					

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Deferasirox**

**Initial application**

Applications only from a haematologist. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia
<b>and</b>	
<input type="checkbox"/>	Deferasirox is to be given at a daily dose not exceeding 40 mg/kg/day
<b>and</b>	
<input type="checkbox"/>	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*
<b>or</b>	
<input type="checkbox"/>	Treatment with deferiprone has resulted in severe persistent vomiting or diarrhoea
<b>or</b>	
<input type="checkbox"/>	Treatment with deferiprone has resulted in arthritis
<b>or</b>	
<input type="checkbox"/>	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)

**Renewal**

Current approval Number (if known):.....

Applications only from a haematologist. Approvals valid for 2 years.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	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
<b>or</b>	
<input type="checkbox"/>	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 the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)



## Special Foods

**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER** Reg No: .....

Reg No: .....      First Names: .....      First Names: .....

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**Carbohydrate** (Moducal; Polycal)

**Initial application — Cystic fibrosis or kidney disease**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years.

**Prerequisites**(tick boxes where appropriate)

Cystic fibrosis

or

Chronic kidney disease

**Initial application — Indications other than cystic fibrosis or renal failure**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

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

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.

**Initial application — Inborn errors of metabolism**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The patient has inborn errors of metabolism

**Renewal — Cystic fibrosis or renal failure**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years.

**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

and

General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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Reg No: .....	First Names: .....	First Names: .....
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Fax Number: .....	.....	Fax Number: .....

**Carbohydrate** (Moducal; Polycal) - *continued*

**Renewal — Indications other than cystic fibrosis or renal failure**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

<input type="checkbox"/>	The treatment remains appropriate and the patient is benefiting from treatment
<b>and</b>	General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Carbohydrate and Fat** (Duocal Super Soluble Powder)

**Initial application — Cystic fibrosis**  
Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years.  
**Prerequisites**(tick boxes where appropriate)

Infant or child aged four years or under  
**and**  
 Cystic fibrosis

**Initial application — Indications other than cystic fibrosis**  
Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.  
**Prerequisites**(tick boxes where appropriate)

Infant or child aged four years or under  
**and**  
 Cancer in children  
**or**  
 Faltering growth  
**or**  
 Bronchopulmonary dysplasia  
**or**  
 Premature and post premature infants

**Renewal — Cystic fibrosis**  
Current approval Number (if known):.....  
Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years.  
**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment  
**and**  
General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

**Renewal — Indications other than cystic fibrosis**  
Current approval Number (if known):.....  
Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.  
**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment  
**and**  
General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

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Fax Number: .....      Fax Number: .....

**Fat** (Calogen; Liquigen; MCT oil (Nutricia))

**Initial application — Inborn errors of metabolism**  
Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified.  
**Prerequisites**(tick box where appropriate)

The patient has an inborn error of metabolism

**Initial application — Indications other than inborn errors of metabolism**  
Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.  
**Prerequisites**(tick boxes where appropriate)

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  
 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.

**Renewal — Indications other than inborn errors of metabolism**  
Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.  
**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment  
**and**  
General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Protein** (Protifar; Promod; Resource Beneprotein)

**Initial application**  
Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

Protein losing enteropathy

or

High protein needs

or

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.

**Renewal**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

and

General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Diabetic products** (Diason RTH; Glucerna Select RTH; Diasip; Glucerna Select; Resource Diabetic)

**Initial application**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick box where appropriate)

The patient is a type I or and II diabetic who is suffering weight loss and malnutrition that requires nutritional support

**Renewal**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

**and**  
General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Fat Modified Products** (Monogen)

**Initial application — Inborn errors of metabolism**  
Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified.  
**Prerequisites**(tick box where appropriate)

The patient has an inborn error of metabolism

**Initial application — Indications other than errors of inborn metabolism**  
Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.  
**Prerequisites**(tick boxes where appropriate)

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.

**Renewal**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.  
**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment  
and  
General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

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**Paediatric Product For Children Awaiting Liver Transplant** (Heparon Junior)

**Initial application**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years.

**Prerequisites**(tick box where appropriate)

The patient is a child (up to 18 years) who requires a liver transplant

**Renewal**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years.

**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

**and**  
General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

I confirm the above details are correct and that in signing this form I understand I may be audited.

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Fax Number: .....	.....	Fax Number: .....

**Paediatric Product For Children With Chronic Renal Failure** (Kindergen)

**Initial application**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years.

**Prerequisites**(tick box where appropriate)

The patient is a child (up to 18 years) with acute or chronic kidney disease

**Renewal**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years.

**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

**and**  
General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

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**Paediatric Products**

**Initial application**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Child is aged one to ten years <b>and</b> <input type="checkbox"/> The child is being fed via a tube or a tube is to be inserted for the purposes of feeding <b>or</b> <input type="checkbox"/> Any condition causing malabsorption <b>or</b> <input type="checkbox"/> Faltering growth in an infant/child <b>or</b> <input type="checkbox"/> Increased nutritional requirements <b>or</b> <input type="checkbox"/> The child is being transitioned from TPN or tube feeding to oral feeding
---

**Renewal**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

<input type="checkbox"/> The treatment remains appropriate and the patient is benefiting from treatment <b>and</b> General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....
---

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**Renal Products** (Nepro; NovaSource Renal; Renilon 7.5; Suplena)

**Initial application**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years.

**Prerequisites**(tick box where appropriate)

The patient has acute or chronic kidney disease

**Renewal**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years.

**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

**and**  
General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

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**Specialised And Elemental Products**

**Initial application**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Malabsorption
or	
<input type="checkbox"/>	Short bowel syndrome
or	
<input type="checkbox"/>	Enterocutaneous fistulas
or	
<input type="checkbox"/>	Eosinophilic oesophagitis
or	
<input type="checkbox"/>	Inflammatory bowel disease
or	
<input type="checkbox"/>	Patients with multiple food allergies requiring enteral feeding

Note: Each of these products is highly specialised and would be prescribed only by an expert for a specific disorder. The alternative is hospitalisation. Elemental 028 Extra is more expensive than other products listed in this section and should only be used where the alternatives have been tried first and/or are unsuitable.

**Renewal**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

<input type="checkbox"/>	The treatment remains appropriate and the patient is benefiting from treatment
and	
General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....	

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Paediatric enteral feed with fibre 0.75 kcal/ml** (Nutrini Low Energy Multi Fibre)

**Initial application**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/> Child aged one to eight years <b>and</b> <input type="checkbox"/> The child has a low energy requirement but normal protein and micronutrient requirements
---

**Renewal**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

<input type="checkbox"/> The treatment remains appropriate and the patient is benefiting from treatment <b>and</b> General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....
---

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**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER** Reg No: .....

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Fax Number: .....      Fax Number: .....

**Standard Supplements**

**Initial application — Children - indications other than exclusive enteral nutrition for Crohn's disease**

Applications from any relevant practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

The patient is under 18 years of age

**and**

The patient has a condition causing malabsorption

**or**

The patient has failure to thrive

**or**

The patient has increased nutritional requirements

**and**

Nutrition goal has been set (eg reach a specific weight or BMI)

**Renewal — Children - indications other than exclusive enteral nutrition for Crohn's disease**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

The patient is under 18 years of age

**and**

The treatment remains appropriate and the patient is benefiting from treatment

**and**

A nutrition goal has been set (eg reach a specific weight or BMI)

**Initial application — Children - exclusive enteral nutrition for Crohn's disease**

Applications only from a gastroenterologist or dietitian on the recommendation of a gastroenterologist. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

The patient is under 18 years of age

**and**

It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease

**and**

Dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)



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**Standard Supplements** - *continued*

**Renewal — Children - exclusive enteral nutrition for Crohn's disease**

Current approval Number (if known):.....

Applications from any relevant practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months.

**Prerequisites**(tick boxes, and write the data requested in the space provided where appropriate)

<input type="checkbox"/> The patient is under 18 years of age <b>and</b> <input type="checkbox"/> It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease <b>and</b> General Practitioners and dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.....
--

**Initial application — Adults**

Applications from any relevant practitioner. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

<p><b>Patient is Malnourished</b></p> <input type="checkbox"/> Patient has a body mass index (BMI) of less than 18.5 kg/m <sup>2</sup> <b>or</b> <input type="checkbox"/> Patient has unintentional weight loss greater than 10% within the last 3-6 months <b>or</b> <input type="checkbox"/> Patient has a BMI of less than 20 kg/m <sup>2</sup> and unintentional weight loss greater than 5% within the last 3-6 months
<b>and</b> <p><b>Patient has not responded to first-line dietary measures over a 4 week period by:</b></p> <input type="checkbox"/> Increasing their food intake frequency (eg snacks between meals) <b>or</b> <input type="checkbox"/> Using high-energy foods (e.g. milkshakes, full fat milk, butter, cream, cheese, sugar etc) <b>or</b> <input type="checkbox"/> Using over the counter supplements (e.g. Complan)
<b>and</b> <input type="checkbox"/> A nutrition goal has been set (e.g. to reach a specific weight or BMI)

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Standard Supplements - continued**

**Renewal — Adults**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

A nutrition goal has been set (eg reach a specific weight or BMI)

and

**Patient is Malnourished**

Patient has a body mass index (BMI) of less than 18.5 kg/m<sup>2</sup>

or

Patient has unintentional weight loss greater than 10% within the last 3-6 months

or

Patient has a BMI of less than 20 kg/m<sup>2</sup> and unintentional weight loss greater than 5% within the last 3-6 months

**Initial application — Short-term medical condition**

Applications from any relevant practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

Is being fed via a nasogastric tube or a nasogastric tube is to be inserted for feeding

or

Malignancy and is considered likely to develop malnutrition as a result

or

Is undergoing a bone marrow transplant

or

Tempomandibular surgery or glossectomy

or

Pregnant

and

Patient is in early pregnancy (< 13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum

or

Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight

or

Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Standard Supplements** - *continued*

**Renewal — Short-term medical condition**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 1 year.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Is being fed via a nasogastric tube
<b>or</b>	
<input type="checkbox"/>	Malignancy and is considered likely to develop malnutrition as a result
<b>or</b>	
<input type="checkbox"/>	Has undergone a bone marrow transplant
<b>or</b>	
<input type="checkbox"/>	Tempomandibular surgery or glossectomy
<b>or</b>	
<input type="checkbox"/>	Pregnant
<b>and</b>	
<input type="checkbox"/>	Patient is in early pregnancy (< 13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum
<b>or</b>	
<input type="checkbox"/>	Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight
<b>or</b>	
<input type="checkbox"/>	Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met

I confirm the above details are correct and that in signing this form I understand I may be audited.

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**Standard Supplements** - *continued*

**Initial application — Long-term medical condition**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube - refer to specific medical condition criteria)
or	
<input type="checkbox"/>	Cystic Fibrosis
or	
<input type="checkbox"/>	Liver disease
or	
<input type="checkbox"/>	Chronic Renal failure
or	
<input type="checkbox"/>	Inflammatory bowel disease
or	
<input type="checkbox"/>	Chronic obstructive pulmonary disease with hypercapnia
or	
<input type="checkbox"/>	Short bowel syndrome
or	
<input type="checkbox"/>	Bowel fistula
or	
<input type="checkbox"/>	Severe chronic neurological conditions
or	
<input type="checkbox"/>	Epidermolysis bullosa
or	
<input type="checkbox"/>	AIDS (CD4 count < 200 cells/mm <sup>3</sup> )
or	
<input type="checkbox"/>	Chronic pancreatitis

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Standard Supplements** - *continued*

**Renewal — Chronic disease OR tube feeding for patients who have previously been funded under Special Authority forms SA0702 or SA0583**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube - refer to specific medical condition criteria)
<b>or</b>	
<input type="checkbox"/>	Cystic Fibrosis
<b>or</b>	
<input type="checkbox"/>	Liver disease
<b>or</b>	
<input type="checkbox"/>	Chronic Renal failure
<b>or</b>	
<input type="checkbox"/>	Inflammatory bowel disease
<b>or</b>	
<input type="checkbox"/>	Chronic obstructive pulmonary disease with hypercapnia
<b>or</b>	
<input type="checkbox"/>	Short bowel syndrome
<b>or</b>	
<input type="checkbox"/>	Bowel fistula
<b>or</b>	
<input type="checkbox"/>	Severe chronic neurological conditions

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**High Calorie Products** (Two Cal HN; Nutrison Concentrated)

**Initial application — Cystic fibrosis**  
Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years.  
**Prerequisites**(tick boxes where appropriate)

Cystic fibrosis  
**and**  
 Other lower calorie products have been tried  
**and**  
 Patient has substantially increased metabolic requirements

**Initial application — Indications other than cystic fibrosis**  
Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.  
**Prerequisites**(tick boxes where appropriate)

Any condition causing malabsorption  
**or**  
 Faltering growth in an infant/child  
**or**  
 Increased nutritional requirements  
**or**  
 Fluid restricted

**and**  
 Other lower calorie products have been tried  
**and**  
 Patient has substantially increased metabolic requirements or is fluid restricted

**Renewal — Cystic fibrosis**  
Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years.  
**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment  
**and**  
General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**High Calorie Products** (Two Cal HN; Nutrison Concentrated) - *continued*

**Renewal — Indications other than cystic fibrosis**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

<input type="checkbox"/>	The treatment remains appropriate and the patient is benefiting from treatment
<b>and</b>	General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Food Thickeners** (Karicare Food Thickener; Nutilis)

**Initial application**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick box where appropriate)

The patient has motor neurone disease with swallowing disorder

**Renewal**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

**and**  
General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)



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**Gluten Free Foods** (Bakels Gluten Free Health Bread Mix; Horleys Bread Mix; Horleys Flour; NZB Low Gluten Bread Mix; Orgran; Healtheries Simple Baking Mix)

**Initial application — all patients**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick boxes where appropriate)

<b>or</b>	<input type="checkbox"/> Gluten enteropathy has been diagnosed by biopsy
	<input type="checkbox"/> Patient suffers from dermatitis herpetiformis

**Initial application — paediatric patients diagnosed by ESPGHAN criteria**

Applications only from a paediatric gastroenterologist. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

The paediatric patient fulfils ESPGHAN criteria for biopsy free diagnosis of coeliac disease

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Foods and Supplements For Inborn Errors Of Metabolism**

**Initial application**

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

**Prerequisites**(tick box where appropriate)

Patient requires dietary management of inherited metabolic disorders

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Infant Formulae - For Williams Syndrome** (Locasol)

**Initial application**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick box where appropriate)

The patient is an infant suffering from Williams Syndrome and associated hypercalcaemia

**Renewal**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year.

**Prerequisites**(tick box, and write the data requested in the space provided where appropriate)

The treatment remains appropriate and the patient is benefiting from treatment

**and**  
General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted .....

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Amino acid formula** (Alfamino Junior; Elecare; Neocate)

**Initial application — Infants under 12 months of age**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	History of anaphylaxis to cow's milk protein formula or dairy products
or	
<input type="checkbox"/>	Eosinophilic oesophagitis
or	
<input type="checkbox"/>	Ultra-short gut
or	
<input type="checkbox"/>	Severe Immune deficiency
or	
<input type="checkbox"/>	Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate
or	
<input type="checkbox"/>	Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption
and	
<input type="checkbox"/>	The patient has a valid Special Authority approval for extensively hydrolysed formula: approval number
or	
<input type="checkbox"/>	Patient has IgE mediated allergy

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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**Amino acid formula** (Alfamino Junior; Elecare; Neocate) - *continued*

**Initial application — Children 12 months of age and over**

Applications only from a paediatrician, paediatric gastroenterologist, paediatric immunologist or dietitian on the recommendation of a paediatrician, paediatric gastroenterologist or paediatric immunologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- Applicant is a paediatrician, paediatric gastroenterologist or paediatric immunologist  
or  
 Applicant is a dietitian and confirms that a paediatrician, paediatric gastroenterologist or paediatric immunologist has been consulted within the last 12 months and has recommended treatment for the patient

and

- History of anaphylaxis to cow's milk protein formula or dairy products  
or  
 Eosinophilic oesophagitis  
or  
 Ultra-short gut  
or  
 Severe Immune deficiency  
or  
 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate

Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption

and

- The patient has a valid Special Authority approval for extensively hydrolysed formula: approval number  
or  
 Patient has IgE mediated allergy

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

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**Amino acid formula** (Alfamino Junior; Elecare; Neocate) - *continued*

**Renewal — Infants up to 12 months of age**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

Patient has IgE mediated allergy

**and**

Patient remains allergic to cow's milk

**and**

An assessment as to whether the infant can be transitioned to a cow's 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

**and**

It has been more than three months from the previous approval

**or**

Patient has non IgE mediated severe gastrointestinal intolerance (including eosinophilic oesophagitis, ultra-short gut and severe immune deficiency)

**and**

An assessment as to whether the infant can be transitioned to a cow's 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

**and**

It has been more than three months from the previous approval

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**Amino acid formula** (Alfamino Junior; Elecare; Neocate) - *continued*

**Renewal — Children 12 months of age and over**

Current approval Number (if known):.....

Applications only from a paediatrician, paediatric gastroenterologist, paediatric immunologist or dietitian on the recommendation of a paediatrician, paediatric gastroenterologist or paediatric immunologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- Applicant is a paediatrician, paediatric gastroenterologist or paediatric immunologist  
or  
 Applicant is a dietitian and confirms that a paediatrician, paediatric gastroenterologist or paediatric immunologist has been consulted within the last 12 months and has recommended treatment for the patient

and

- History of anaphylaxis to cow's milk protein formula or dairy products  
or  
 Eosinophilic oesophagitis  
or  
 Ultra-short gut  
or  
 Severe Immune deficiency  
or  
 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate

- Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption

and

- The patient has a valid Special Authority approval for extensively hydrolysed formula: approval number  
or  
 Patient has IgE mediated allergy

**Initial application — for patients who have a current funding under Special Authority form SA1557**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 months.

**Prerequisites**(tick boxes where appropriate)

- Patient has a valid Special Authority approval for extensively hydrolysed formula (SA1557)  
and  
 Extensively hydrolysed formula (Aptamil Gold+ Pepti Junior, AllerPro SYNEO 1 and 2) is unable to be supplied 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 Special Authority form SA1557. There is no renewal criteria under this restriction.

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**Extensively hydrolysed formula**

**Initial application**

Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes, and write the data requested in the space provided 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 malabsorption

**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

**and**

The infant is currently receiving funded amino acid formula

**and**

The infant is to be trialled on, or transitioned to, an extensively hydrolysed formula

**and**

General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted .....

Note: A reasonable trial is defined as a 2-4 week trial, or signs of an immediate IgE mediated allergic reaction.

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

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**Extensively hydrolysed formula** - *continued*

**Renewal**

Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes, and write the data requested in the space provided where appropriate)

<b>and</b>	<input type="checkbox"/> An assessment as to whether the infant can be transitioned to a cows milk protein or soy infant formula has been undertaken
<b>and</b>	<input type="checkbox"/> The outcome of the assessment is that the infant continues to require an extensively hydrolysed infant formula
General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted .....	

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

**APPLICANT** (stamp or sticker acceptable)      **PATIENT NHI:** .....      **REFERRER** Reg No: .....

Reg No: .....      First Names: .....      First Names: .....

Name: .....      Surname: .....      Surname: .....

Address: .....      DOB: .....      Address: .....

.....      Address: .....      .....

.....      .....

Fax Number: .....      Fax Number: .....

**Enteral liquid peptide formula** (Nutrini Peptisorb; Nutrini Peptisorb Energy)

**Initial application**  
Applications only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months.  
**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.

**Renewal**  
Current approval Number (if known):.....

Applications only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months.  
**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

**and**

General practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: ..... Date: .....  
Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT NHI:</b> .....	<b>REFERRER</b> Reg No: .....
Reg No: .....	First Names: .....	First Names: .....
Name: .....	Surname: .....	Surname: .....
Address: .....	DOB: .....	Address: .....
.....	Address: .....	.....
.....	.....	.....
Fax Number: .....	.....	Fax Number: .....

**Paediatric oral/enteral feed 1 kcal/ml (Infatrini)**

**Initial application**

Applications only from a paediatrician, dietitian or general practitioner on the recommendation of a paediatrician or dietitian. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient is fluid restricted or volume intolerant and has been diagnosed with faltering growth
<b>and</b>	
<input type="checkbox"/>	Patient is under the care of a paediatrician or dietitian who has recommended treatment with a high energy infant formula
<b>and</b>	
<input type="checkbox"/>	Patient is under 18 months of age or weighs less than 8 kg

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.

**Renewal**

Current approval Number (if known):.....

Applications only from a paediatrician, dietitian or general practitioner on the recommendation of a paediatrician or dietitian. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

<input type="checkbox"/>	Patient continues to be fluid restricted or volume intolerant and has faltering growth
<b>and</b>	
<input type="checkbox"/>	Patient is under the care of a hospital paediatrician or dietitian who has recommended treatment with a high energy infant formula
<b>and</b>	
<input type="checkbox"/>	Patient is under 18 months of age or weighs less than 8 kg

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 the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

<b>APPLICANT</b> (stamp or sticker acceptable)	<b>PATIENT NHI:</b> .....	<b>REFERRER</b> Reg No: .....
Reg No: .....	First Names: .....	First Names: .....
Name: .....	Surname: .....	Surname: .....
Address: .....	DOB: .....	Address: .....
.....	Address: .....	.....
.....	.....	.....
Fax Number: .....	.....	Fax Number: .....

**High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (KetoCal)**

**Initial application**

Applications only from a metabolic physician or paediatric neurologist. Approvals valid for 3 months.

**Prerequisites**(tick box where appropriate)

The patient has intractable epilepsy, pyruvate dehydrogenase deficiency or glucose transported type-1 deficiency and other conditions requiring a ketogenic diet

**Renewal**

Current approval Number (if known):.....

Applications only from a metabolic physician or paediatric neurologist. Approvals valid for 2 years.

**Prerequisites**(tick box where appropriate)

The patient is on a ketogenic diet and the patient is benefiting from the diet

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)

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