SPECIAL AUTHORITY FORMS
October 2026

Therapeutic Groups

THE SPECIAL AUTHORITY SYSTEM 3
Alimentary Tract and Metabolism 5
Blood and Blood Forming Organs 44
Cardiovascular System 57
Dermatologicals 81
Genito-Urinary System 89
Hormone Preparations - Systemic Excluding Contraceptive Hormones 93
Infections - Agents for Systemic Use 105
Musculoskeletal System 139
Nervous System 145
Oncology Agents and Immunosuppressants 176
Respiratory System and Allergies 383
Sensory Organs 396
Various 402
Special Foods 405
Index of form numbers 441
Index of titles 443

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:

Health New Zealand, Private Bag 3015, Wanganui
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

Product (Form No)	**Panel**
Ledipasvir with sofosbuvir (SA1605)	Hepatitis C Treatment Panel (HepCTP)

Alimentary Tract and Metabolism

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

Address: .....

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REFERRER Reg No: .....

First Names: .....

Surname: .....

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Budesonide - Cap 3 mg Controlled Release

Initial application — Crohn's disease
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
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 without further renewal unless notified.
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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

Address: .....

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REFERRER Reg No: .....

First Names: .....

Surname: .....

Address: .....

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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 — gut Graft versus Host disease

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

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

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

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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Glyceryl trinitrate Oint 0.2%

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

☐ The patient has a chronic anal fissure that has persisted for longer than three weeks

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

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Name:	Surname:	Surname: .....
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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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Name:	Surname:	Surname: .....
Address:	DOB:	Address: .....
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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

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
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Name:	Surname:	Surname: .....
Address:	DOB:	Address: .....
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Dulaglutide

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Patient has type 2 diabetes

and

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

and

☐ Funded dulaglutide is not to be prescribed in combination with funded empagliflozin/ empagliflozin with metformin unless receiving funded empagliflozin / empagliflozin with metformin hydrochloride for the treatment of heart failure

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: 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: .....
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Liraglutide

Initial application — Type 2 Diabetes
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Patient has type 2 diabetes

and

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

and

☐ Funded liraglutide is not to be prescribed in combination with funded empagliflozin/ empagliflozin with metformin unless receiving funded empagliflozin / empagliflozin with metformin hydrochloride for the treatment of heart failure

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

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

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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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 type 2 diabetes
- **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
- **or**
- ☐ Patient has previously had an initial approval for a GLP-1 agonist and is changing funded treatment to an SGLT2i
- **and**
- ☐ Funded empagliflozin or empagliflozin with metformin hydrochloride is not to be prescribed in combination with a funded GLP-1 agonist unless for the treatment of heart failure

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: 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: .....
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Insulin Pump Consumables

Initial application — type 1 diabetes
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
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

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

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: 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: .....
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Continuous glucose monitor (standalone)

Initial application — type 1 diabetes
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
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

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
Reg No:	First Names:	First Names: .....
Name:	Surname:	Surname: .....
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Continuous glucose monitor (interoperable)

Initial application — type 1 diabetes
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
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

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

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

SA2448 - Ursodeoxycholic Acid

Alagille syndrome or progressive familial intrahepatic cholestasis - Initial application 19
Chronic severe drug induced cholestatic liver injury - Initial application 19
Chronic severe drug induced cholestatic liver injury - Renewal 20
Haematological Transplant - Initial application 19
Pregnancy - Initial application 19
Pregnancy/Primary biliary cholangitis - Renewal 20
Primary biliary cholangitis - Initial application 19
Total parenteral nutrition induced cholestasis - Initial application 20
Total parenteral nutrition induced cholestasis - Renewal 20
Prevention of sinusoidal obstruction syndrome - Initial application 20

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

Address: .....

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REFERRER Reg No: .....

First Names: .....

Surname: .....

Address: .....

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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.

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

Address: .....

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REFERRER Reg No: .....

First Names: .....

Surname: .....

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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)

☐ Paediatric patient has developed abnormal liver function as indicated on testing which is likely to be induced by Total Parenteral Nutrition (TPN)

and

☐ 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

Initial application — prevention of sinusoidal obstruction syndrome
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick box where appropriate)

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

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

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

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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Methylnaltrexone bromide

Initial application — Opioid induced constipation
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ The patient is receiving palliative care

and

or

☐ Oral and rectal treatments for opioid induced constipation are ineffective

☐ 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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APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
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Name:	Surname:	Surname: .....
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Sodium picosulfate

Initial application
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

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

and

☐ The patient would otherwise require a high-volume bowel cleansing preparation or hospital admission

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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Name:	Surname:	Surname: .....
Address:	DOB:	Address: .....
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Galsulfase

Initial application
Applications only from a metabolic physician. Approvals valid for 12 months.
Prerequisites(tick boxes where appropriate)

☐ The patient has been diagnosed with mucopolysaccharidosis VI

and

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

or

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

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

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

and

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

and

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

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

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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

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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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

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

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Betaine

Initial application
Applications only from a metabolic physician. Approvals valid for 12 months.
Prerequisites(tick boxes where appropriate)

☐ The patient has a confirmed diagnosis of homocystinuria

and

☐ A cystathionine beta-synthase (CBS) deficiency

or

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

or

☐ A disorder of intracellular cobalamin metabolism

and

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

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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Sapropterin 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 sapropterin is required to support management of PKU during pregnancy

and

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

and

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

and

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

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 sapropterin with a clinically appropriate reduction in phenylalanine levels to support management of PKU during pregnancy

or

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

and

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

or

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

or

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

and

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

and

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

and

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

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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)

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

and

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

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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)

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

and

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

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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)

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

and

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

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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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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

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

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Trientine

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has confirmed Wilson disease

and

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

and

- ☐ Treatment with zinc has been trailled 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.

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Nitisinone

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

☐ Patient requires nitisinone for the management of inherited metabolic disorders

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

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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)

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Vitabdeck

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Patient has cystic fibrosis with pancreatic insufficiency

or

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

or

☐ Patient has severe malabsorption syndrome

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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

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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)

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

or

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

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Ferric carboxymaltose

Initial application — Anaemia
Applications from any relevant practitioner. Approvals valid for 3 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has been diagnosed with anaemia

and

- ☐ Serum ferritin level is 20 mcg/L or less

or

- ☐ Serum ferritin is between 20 and 50 mcg/L

and

- ☐ C-Reactive Protein (CRP) is at least 5 mg/L

or

- ☐ Patient has chronic inflammatory disease with symptoms of anaemia despite normal iron levels

and

- ☐ Oral iron treatment has proven ineffective

or

- ☐ Oral iron treatment has resulted in dose-limiting intolerance

or

- ☐ 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)

- ☐ 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

and

- ☐ A trial (or re-trial) with oral iron is clinically inappropriate

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

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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 a internal medicine physician, obstetrician, gynaecologist or anaesthetist. Approvals valid for 3 months.

Prerequisites(tick boxes where appropriate)

☐ Patient has been diagnosed with iron-deficiency anaemia

and

☐ Patient has been compliant with oral iron treatment and treatment has proven ineffective

or

☐ Treatment with oral iron has resulted in dose-limiting intolerance

or

☐ 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

or

☐ 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 a internal medicine physician, obstetrician, gynaecologist or anaesthetist. Approvals valid for 3 months.

Prerequisites(tick boxes where appropriate)

☐ Patient continues to have iron-deficiency anaemia

and

☐ A re-trial with oral iron is clinically inappropriate

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Blood and Blood Forming Organs

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

Initial application — chronic renal failure
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ Patient in chronic renal failure
- **and** ☐ Haemoglobin is less than or equal to 100g/L
- **and**
  - ☐ Patient does not have diabetes mellitus
  - **and** ☐ Glomerular filtration rate is less than or equal to 30ml/min
  - **or**
  - ☐ Patient has diabetes mellitus
  - **and** ☐ Glomerular filtration rate is less than or equal to 45ml/min
  - **or** ☐ Patient is on haemodialysis or peritoneal dialysis

Initial application — myelodysplasia
Applications from any specialist. Approvals valid for 2 months.
Prerequisites(tick boxes where appropriate)

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

Note: Indication marked with * is an unapproved indication

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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)

- ☐ The patient's transfusion requirement continues to be reduced with erythropoietin treatment

and

- ☐ Transformation to acute myeloid leukaemia has not occurred

and

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

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 trialled and failed after therapy of 3 months each (or 1 month for rituximab)

and

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

or

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

or

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

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 trialled and failed after therapy of 3 months each (or 1 month for rituximab)

and

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

or

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

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 trialled and failed after therapy of at least 3 months duration

and

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

or

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

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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)

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

and

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

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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

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)

- ☐ 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

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)

- ☐ Patient is continuing to benefit from treatment

and

- ☐ Treatment continues to be clinically appropriate

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Ticagrelor *- continued*

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**

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)

- ☐ 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

Initial application — acute minor stroke or high-risk transient ischemic attack (TIA)*
Applications from any relevant practitioner. Approvals valid for 1 month.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has been diagnosed with a minor stroke (NIHSS† score 3 or less), high-risk TIA (ABCD2 score 4 or more) or Crescendo TIA
- **and**
  - ☐ Patient is expected to be a poor metaboliser of clopidogrel, with documented clinical rationale
  - **or**
  - ☐ Patient is allergic to clopidogrel**
- **and**
- ☐ Ticagrelor to be prescribed for a maximum of 21 days following minor stroke or TIA

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Ticagrelor *- continued*

Renewal — subsequent minor stroke or TIA, or Crescendo TIA

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

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

Prerequisites(tick box where appropriate)

☐ Patient has been diagnosed with a minor stroke (NIHSS score 3 or less) or high-risk transient ischemic attack (ABCD2 score 4 or more) or Crescendo TIA

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.
Note: Note:NIHSS† National Institutes of Health Stroke Scale.

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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 from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ Prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk greater than or equal to 20%*)

or

- ☐ Peripheral blood stem cell mobilisation in patients undergoing haematological transplantation

or

- ☐ Peripheral blood stem cell mobilisation or bone marrow donation from healthy donors for transplantation

or

- ☐ Treatment of severe chronic neutropenia (ANC < 0.5 $\times 10^9$/L)

or

- ☐ Treatment of drug-induced prolonged neutropenia (ANC < 0.5 $\times 10^9$/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.

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Pegfilgrastim

Initial application
Applications from any relevant practitioner. 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

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Propranolol

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

- ☐ For the treatment of a child under 12 years with an haemangioma causing functional impairment (not for cosmetic reasons only)

or

- ☐ For the treatment of a child under 12 years with cardiac arrthymias 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)

- ☐ For the treatment of a child under 12 years with an haemangioma causing functional impairment (not for cosmetic reasons only)

or

- ☐ For the treatment of a child under 12 years with cardiac arrthymias or congenital cardiac abnormalities

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Eplerenone

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Patient has heart failure with ejection fraction less than 40%

and

☐ Patient is intolerant to optimal dosing of spironolactone

or

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

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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^2 at treatment initiation

and

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

or

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

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^2

and

- ☐ Patient has not undergone a kidney transplant

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Hydralazine

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ For the treatment of refractory hypertension

or

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

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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^{-5})

and

☐ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

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

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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^{-5})

and

☐ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

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.

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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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^{-5})

and

☐ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

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.

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Bosentan *- 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 bosentan treatment according to a validated PAH risk stratification tool**

Note: ** 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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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^{-5})

and

- ☐ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

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.

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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^{-5})

and

☐ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

or

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

or

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

or

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

or

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

and

☐ Ambrisentan is to be used as PAH dual therapy

and

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

or

☐ Patient has experienced intolerable side effects on bosentan

or

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

or

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

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

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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^{-5})

and

☐ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

or

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

or

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

or

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

or

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

and

☐ Ambrisentan is to be used as PAH triple therapy

and

☐ Patient is on the lung transplant list

or

☐ Patient is presenting in NYHA/WHO functional class IV

and

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

or

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

and

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

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

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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 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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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^{-5})

and

- ☐ PAH is non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

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.

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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)

☐ Patient has a documented history of traumatic or non-traumatic spinal cord injury

and

☐ 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: Indications marked with * are Unapproved Indications.
** 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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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^{-5})

and

☐ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

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.

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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^{-5})

  and

  - ☐ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

    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.

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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^{-5})

and

☐ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

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.

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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 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^{-5})

and

☐ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

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.

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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^{-5})

and

☐ PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH

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.

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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

APPLICANT (stamp or sticker acceptable)

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Isotretinoin

Initial application
Applications from any relevant practitioner. Approvals valid for 1 year.
Prerequisites(tick boxes where appropriate)

- ☐ Applicant is a vocationally registered dermatologist, paediatrician, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice

and

- ☐ Applicant has an up to date knowledge of the safety issues around isotretinoin and is competent to prescribe isotretinoin

and

- ☐ 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

or

- ☐ Patient is not of child bearing potential

or

- ☐ Patient is a child and it is considered not appropriate to exclude pregnancy or start contraceptives or undertake pregnancy-related isotretinoin counselling

Renewal

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

Applications from any relevant practitioner. Approvals valid for 1 year.
Prerequisites(tick boxes where appropriate)

- ☐ 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

or

- ☐ Patient is not of child bearing potential

or

- ☐ Patient is a child and it is considered not appropriate to exclude pregnancy or start contraceptives or undertake pregnancy-related isotretinoin counselling

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

- ☐ The patient has neuroblastoma

and

- ☐ 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

or

- ☐ Patient is not of child bearing potential

or

- ☐ Patient is a child and it is considered not appropriate to exclude pregnancy or start contraceptives or undertake pregnancy-related isotretinoin counselling

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Isotretinoin *- continued*

Renewal — Neuroblastoma

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

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

Prerequisites(tick boxes where appropriate)

☐ The patient has neuroblastoma

and

☐ 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

or

☐ Patient is not of child bearing potential

or

☐ Patient is a child and it is considered not appropriate to exclude pregnancy or start contraceptives or undertake pregnancy-related isotretinoin counselling

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Ivermectin

Initial application — Scabies
Applications from any relevant practitioner. Approvals valid for 1 month.
Prerequisites(tick boxes where appropriate)

- ☐ The person has a severe scabies hyperinfestation (Crusted/ Norwegian scabies)

or

- ☐ The person has a confirmed diagnosis of scabies or is a close contact of a scabies case

and

- ☐ The person is unable to complete topical therapy

or

- ☐ 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)

- ☐ Filariasis

or

- ☐ Cutaneous larva migrans (creeping eruption)

or

- ☐ Strongyloidiasis

or

- ☐ The individual has a travel or residence history that requires presumptive parasite treatment

Renewal — Scabies

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

Applications from any relevant practitioner. Approvals valid for 1 month.
Prerequisites(tick boxes where appropriate)

- ☐ The person has a severe scabies hyperinfestation (Crusted/ Norwegian scabies)

or

- ☐ The person has a confirmed diagnosis of scabies or is a close contact of a scabies case

and

- ☐ The person is unable to complete topical therapy

or

- ☐ Previous treatment with topical therapy has been tried and not cleared the infestation

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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)

- ☐ Filariasis

or

- ☐ Cutaneous larva migrans (creeping eruption)

or

- ☐ Strongyloidiasis

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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)

☐ Patient has atopic dermatitis on the face

and

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

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

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Acitretin

Initial application
Applications from any relevant practitioner. Approvals valid for 1 year.
Prerequisites(tick boxes where appropriate)

☐ Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice

and

☐ Applicant has an up to date knowledge of the safety issues around acitretin and is competent to prescribe acitretin

and

☐ 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

or

☐ 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)

☐ 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

or

☐ 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)

☐ Patient has atopic dermatitis on the eyelid

and

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

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

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Genito-Urinary System

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

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Patient has symptomatic benign prostatic hyperplasia

and

or

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

☐ Symptoms are not adequately controlled with non-selective alpha blockers

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

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Tamsulosin

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Patient has symptomatic benign prostatic hyperplasia

and

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

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

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Potassium Citrate

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

☐ The patient has recurrent calcium oxalate urolithiasis

and

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

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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Hormone Preparations - Systemic Excluding Contraceptive Hormones

APPLICANT (stamp or sticker acceptable)

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Cinacalcet

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 arteriolopathy)
- **and**
- ☐ The patient has symptomatic (e.g. painful skin ulcers) hypercalcaemia (serum calcium greater than or equal to 3 mmol/L)
- **and**
- ☐ The patient's condition has not responded to previous first-line treatments including bisphosphonates and sodium thiosulfate

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.

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Cinacalcet *- continued*

Initial application — secondary or tertiary hyperparathyroidism
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

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

and

- ☐ Patient is on renal replacement therapy

and

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

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)

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

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Propylthiouracil

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

☐ The patient has hyperthyroidism

and

☐ 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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SA2032 - Somatropin

Prader-Willi syndrome - Initial application 101
Prader-Willi syndrome - Renewal 101
Turner syndrome - Initial application 98
Turner syndrome - Renewal 99
Adults and adolescents - Initial application 102
Adults and adolescents - Renewal 103
Growth hormone deficiency in children - Initial application 98
Growth hormone deficiency in children - Renewal 98
Short stature due to chronic renal insufficiency - Initial application 100
Short stature due to chronic renal insufficiency - Renewal 100
Short stature without growth hormone deficiency - Initial application 99
Short stature without growth hormone deficiency - Renewal 99

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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

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

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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)

- ☐ 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)

and

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

and

- ☐ A current bone age is 14 years or under

and

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

and

- ☐ No malignancy has developed since starting growth hormone

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)

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

and

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

and

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

and

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

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)

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

and

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

and

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

and

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

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

or

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

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: .....

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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

- ☐ The patient has a diagnosis of Prader-Willi syndrome that has been confirmed by genetic testing or clinical scoring criteria

and

- ☐ The patient is aged six months or older

and

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

and

- ☐ Sleep studies or overnight oximetry have been performed and there is no obstructive sleep disorder requiring treatment, or if an obstructive sleep disorder is found, it has been adequately treated under the care of a paediatric respiratory physician and/or ENT surgeon

and

- ☐ The patient is aged two years or older

and

- ☐ There is no evidence of type II diabetes or uncontrolled obesity defined by BMI that has increased by greater than or equal to 0.5 standard deviations in the preceding 12 months

or

- ☐ The patient is aged between six months and two years and a thorough upper airway assessment is planned to be undertaken prior to treatment commencement and at six to 12 weeks following treatment initiation

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)

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

and

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

and

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

and

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

and

- ☐ No malignancy has developed after growth hormone therapy was commenced

and

- ☐ The patient has not developed type II diabetes or uncontrolled obesity as defined by BMI that has increased by greater than or equal to 0.5 standard deviations in the preceding 12 months

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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.

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

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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.

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APPLICATION FOR WAIVER OF RULE BY SPECIAL AUTHORITY

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
Reg No:	First Names:	First Names: .....
Name:	Surname:	Surname: .....
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Cabergoline

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Hyperprolactinemia
or
☐ Acromegaly*
or
☐ 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)

☐ 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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

Infections - Agents for Systemic Use

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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Albendazole

Initial application
Applications only from a relevant specialist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ The individual has hydatids

or

☐ The individual has a travel or residence history that requires presumptive parasite treatment

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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APPLICATION FOR WAIVER OF RULE BY SPECIAL AUTHORITY

Form SA1683
October 2026

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

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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

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICATION FOR WAIVER OF RULE BY SPECIAL AUTHORITY

Form SA1857
October 2026

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

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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.

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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.

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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.

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Sulfadiazine

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ For the treatment of toxoplasmosis in patients with HIV for a period of 3 months

or

- ☐ For pregnant patients for the term of the pregnancy

or

- ☐ 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.

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Paromomycin

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

- ☐ Patient has confirmed cryptosporidium infection

or

- ☐ 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)

- ☐ Patient has confirmed cryptosporidium infection

or

- ☐ For the eradication of Entamoeba histolytica carriage

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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

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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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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)

- ☐ Patient is immunocompromised

and

- ☐ Applicant is part of a multidisciplinary team including an infectious disease specialist

and

- ☐ Patient has proven or probable invasive aspergillus infection

or

- ☐ Patient has possible invasive aspergillus infection

or

- ☐ Patient has fluconazole resistant candidiasis

or

- ☐ Patient has mould strain such as Fusarium spp. and Scedosporium 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)

- ☐ Patient is immunocompromised

and

- ☐ Applicant is part of a multidisciplinary team including an infectious disease specialist

and

- ☐ Patient continues to require treatment for proven or probable invasive aspergillus infection

or

- ☐ Patient continues to require treatment for possible invasive aspergillus infection

or

- ☐ Patient has fluconazole resistant candidiasis

or

- ☐ Patient has mould strain such as Fusarium spp. and Scedosporium spp

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

- ☐ Voriconazole is prescribed by, or recommended by a haematologist, transplant physician, infectious disease specialist, paediatric haematologist or paediatric oncologist

or

- ☐ Prescribing voriconazole is in accordance with a protocol or guideline that has been endorsed by the Health New Zealand - Te Whatu Ora Hospital in the specific settings where there is a greater than 10% risk of invasive fungal infection (IFI)

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

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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)

☐ The patient is at risk of invasive fungal infection

and

☐ Voriconazole is prescribed by, or recommended by a haematologist, transplant physician, infectious disease specialist, paediatric haematologist or paediatric oncologist

or

☐ Prescribing voriconazole is in accordance with a protocol or guideline that has been endorsed by the Health New Zealand - Te Whatu Ora Hospital in the specific settings where there is a greater than 10% risk of invasive fungal infection (IFI)

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

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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)

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Post application to Health New Zealand, Private Bag 3015, Wanganui – email: 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)

☐ 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)

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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

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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)

- ☐ The person has multi-drug resistant tuberculosis (MDR-TB)

and

- ☐ 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.

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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)

☐ The person has multi-drug resistant tuberculosis (MDR-TB)

and

☐ Ministry of Health's Tuberculosis Clinical Network has reviewed the individual case and recommends bedaquiline as part of the treatment regimen

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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

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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

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

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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)

- ☐ Patient has undergone a lung transplant
- **and**
- ☐ The donor was cytomegalovirus positive and the patient is cytomegalovirus negative
- **or**
- ☐ The recipient is cytomegalovirus positive
- **and**
- ☐ Patient has a high risk of CMV disease

Renewal — Lung transplant cytomegalovirus prophylaxis

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

Applications only from a relevant specialist. Approvals valid for 12 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has undergone a lung re-transplant
- **and**
- ☐ The donor was cytomegalovirus positive and the patient is cytomegalovirus negative
- **or**
- ☐ The recipient is cytomegalovirus positive
- **and**
- ☐ Patient has a high risk of CMV disease

Initial application — Cytomegalovirus in immunocompromised patients
Applications only from a relevant specialist. Approvals valid for 3 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient is immunocompromised
- **and**
- ☐ Patient has cytomegalovirus syndrome or tissue invasive disease
- **or**
- ☐ Patient has rapidly rising plasma CMV DNA in absence of disease
- **or**
- ☐ Patient has cytomegalovirus retinitis

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

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Valganciclovir *- continued*

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)

☐ Patient is immunocompromised

and

☐ Patient has cytomegalovirus syndrome or tissue invasive disease

or

☐ Patient has rapidly rising plasma CMV DNA in absence of disease

or

☐ Patient has cytomegalovirus retinitis

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.

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

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Letermovir

Initial application — CMV prophylaxis - post HSCT
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has undergone an allogeneic haematopoietic stem cell transplant

and

- ☐ The patient has confirmed presence of cytomegalovirus-specific antibodies

and

- ☐ Treatment to commence within 28 days of an allogeneic haematopoietic stem cell transplant

and

- ☐ Maximum treatment duration of 100 days post-transplant

Renewal — CMV prophylaxis – second or subsequent HSCT

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

Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has undergone an allogeneic haematopoietic stem cell transplant

and

- ☐ The patient has confirmed presence of cytomegalovirus-specific antibodies

and

- ☐ Treatment to commence within 28 days of an allogeneic haematopoietic stem cell transplant

and

- ☐ Maximum treatment duration of 100 days post-transplant

Initial application — CMV prophylaxis - severe immunosuppression*
Applications only from an infectious disease specialist, clinical microbiologist or any relevant practitioner on the recommendation of a infectious disease specialist or clinical microbiologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has severe immunosuppression requiring prophylaxis of CMV

and

- ☐ Patient is contraindicated to all other funded CMV active oral antiviral agents

or

- ☐ Patient's CMV is resistant to all other funded CMV active oral antiviral agents

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Letermovir *- continued*

Renewal — CMV prophylaxis - severe immunosuppression*

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

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

Prerequisites(tick boxes where appropriate)

☐ Patient has severe immunosuppression requiring prophylaxis of CMV

and

☐ Patient is contraindicated to all other funded CMV active oral antiviral agents

or

☐ Patient's CMV is resistant to all other funded CMV active oral antiviral agents

Note: Indications marked with * are unapproved indications.

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Emtricitabine with tenofovir disoproxil

Initial application — Pre-exposure prophylaxis
Applications from any relevant practitioner. Approvals valid for 24 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has tested HIV negative, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion

and

- ☐ The Practitioner considers the patient is at elevated risk of HIV exposure and use of PrEP is clinically appropriate

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines: https://ashm.org.au/HIV/PrEP/

Renewal — Pre-exposure prophylaxis

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

Applications from any relevant practitioner. Approvals valid for 24 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has tested HIV negative, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion

and

- ☐ The Practitioner considers the patient is at elevated risk of HIV exposure and use of PrEP is clinically appropriate

Note: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines: https://ashm.org.au/HIV/PrEP/

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 appropriate

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

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Emtricitabine with tenofovir disoproxil *- continued*

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 appropriate

or

☐ Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown

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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)

☐ Prevention of maternal foetal transmission

or

☐ 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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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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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)

- ☐ Patient has chronic hepatitis C, genotype 1, 4, 5 or 6 infection

or

- ☐ Patient has chronic hepatitis C and is co-infected with HIV

or

- ☐ Patient has chronic hepatitis C genotype 2 or 3 and has received a liver transplant

and

- ☐ 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)

- ☐ Patient has chronic hepatitis C, genotype 1

and

- ☐ Patient has had previous treatment with pegylated interferon and ribavirin

and

- ☐ Patient has responder relapsed

or

- ☐ Patient was a partial responder

and

- ☐ Patient is to be treated in combination with boceprevir

and

- ☐ Maximum of 48 weeks therapy

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*

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)

- ☐ Patient has chronic hepatitis C, genotype 1

and

- ☐ Patient has had previous treatment with pegylated interferon and ribavirin

and

- ☐ Patient has responder relapsed

or

- ☐ Patient was a partial responder

or

- ☐ Patient received interferon treatment prior to 2004

and

- ☐ Patient is to be treated in combination with boceprevir

and

- ☐ 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)

- ☐ Patient has chronic hepatitis C, genotype 2 or 3 infection

and

- ☐ Maximum of 6 months therapy

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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)

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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 log10 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

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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 allogeneic 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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Fosfomycin

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

☐ Patient has an acute, symptomatic, bacteriologically-proven uncomplicated urinary tract infection (UTI)/cystitis with Escherichia Coli

and

☐ Microbiological testing confirms the pathogen is resistant to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin

or

☐ 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)

☐ Patient has an acute, symptomatic, bacteriologically-proven uncomplicated urinary tract infection (UTI)/cystitis with Escherichia Coli

and

☐ Microbiological testing confirms the pathogen is resistant to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin

or

☐ 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

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Musculoskeletal System

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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

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Teriparatide

Initial application
Applications from any relevant practitioner. Approvals valid for 18 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has severe, established osteoporosis

and

- ☐ The patient has a documented T-score less than or equal to -3.0 (see Notes)

and

- ☐ The patient has had two or more fractures due to minimal trauma

and

- ☐ The patient has experienced at least one symptomatic new fracture after at least 12 months' continuous therapy with a funded antiresorptive agent at adequate doses (see Notes)

Note:

a) The bone mineral density (BMD) measurement used to derive the T-score must be made using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable

b) Antiresorptive agents and their adequate doses for the purposes of this 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 — Osteoporosis
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ The patient has established osteoporosis

and

☐ History of one significant osteoporotic fracture demonstrated radiologically, with a documented T-Score less than or equal to -2.5, that incorporates BMD measured using dual-energy x-ray absorptiometry (DEXA)

or

☐ History of one significant osteoporotic fracture, demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of logistical, technical or pathophysiological reasons

or

☐ History of two significant osteoporotic fractures demonstrated radiologically

or

☐ Documented T-Score less than or equal to -3.0

or

☐ A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm that incorporates BMD measured using DEXA

and

☐ Bisphosphonates are contraindicated because the patient's creatinine clearance or eGFR is less than 35 mL/min

or

☐ The patient has experienced at least two symptomatic new fractures or a BMD loss greater than 2% per year, after at least 12 months' continuous therapy with a funded antiresorptive agent

or

☐ Bisphosphonates result in intolerable side effects

or

☐ Intravenous bisphosphonates cannot be administered due to logistical or technical reasons

Initial application — Hypercalcaemia
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Patient has hypercalcaemia of malignancy

and

☐ Patient has severe renal impairment

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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)

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

and

☐ 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 without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Patient has been diagnosed with gout

and

☐ The patient has a serum urate level greater than 0.36 mmol/l despite treatment with allopurinol at doses of at least 600 mg/day and addition of probenecid at doses of up to 2 g per day or maximum tolerated dose

or

☐ The patient has experienced intolerable side effects from allopurinol such that treatment discontinuation is required and serum urate remains greater than 0.36 mmol/l despite use of probenecid at doses of up to 2 g per day or maximum tolerated dose

or

☐ The patient has renal impairment such that probenecid is contraindicated or likely to be ineffective and serum urate remains greater than 0.36 mmol/l despite optimal treatment with allopurinol

or

☐ 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)

☐ Patient is scheduled to receive cancer therapy carrying an intermediate or high risk of tumour lysis syndrome

and

☐ Patient has a documented history of allopurinol intolerance

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

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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)

- ☐ The patient has amyotrophic lateral sclerosis with disease duration of 5 years or less

and

- ☐ The patient has at least 60 percent of predicted forced vital capacity within 2 months prior to the initial application

and

- ☐ The patient has not undergone a tracheostomy

and

- ☐ The patient has not experienced respiratory failure

and

  - ☐ The patient is ambulatory

  or

  - ☐ The patient is able to use upper limbs

  or

  - ☐ The patient is able to swallow

Renewal

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

Applications from any relevant practitioner. Approvals valid for 18 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has not undergone a tracheostomy

and

- ☐ The patient has not experienced respiratory failure

and

  - ☐ The patient is ambulatory

  or

  - ☐ The patient is able to use upper limbs

  or

  - ☐ The patient is able to swallow

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APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA0906
October 2026

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

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PATIENT NHI: .....

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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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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.

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Lacosamide

Initial application
Applications from any relevant practitioner. Approvals valid for 15 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has focal epilepsy

and

☐ Seizures are not adequately controlled by, or patient has experienced unacceptable side effects from, optimal treatment with all of the following: sodium valproate, topiramate, levetiracetam and any two of carbamazepine, lamotrigine and phenytoin sodium (see Note)

Note: Those of childbearing potential are not required to trial phenytoin sodium, sodium valproate, or topiramate. Those who can father children are not required to trial sodium valproate.

Renewal

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

Applications from any relevant practitioner. Approvals valid for 24 months.
Prerequisites(tick box where appropriate)

☐ 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)

- ☐ Patient has confirmed diagnosis of Dravet syndrome

and

- ☐ Seizures have been inadequately controlled by appropriate courses of sodium valproate, clobazam and at least two of the following: topiramate, levetiracetam, ketogenic diet

Note: Those of childbearing potential are not required to trial sodium valproate or topiramate. Those who can father children are not required to trial sodium valproate.

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)

☐ Control of intractable nausea, vomiting, or inability to swallow saliva in the treatment of malignancy or chronic disease where the patient cannot tolerate or does not adequately respond to oral anti-nausea agents

or

☐ Control of clozapine-induced hypersalivation where trials of at least two other alternative treatments have proven ineffective

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)

☐ The patient has had an initial Special Authority approval for paliperidone depot injection or olanzapine depot injection or aripiprazole depot injection

or

☐ The patient has schizophrenia or other psychotic disorder

and

☐ Has not been able to adhere with treatment using oral atypical antipsychotic agents

and

☐ 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

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Olanzapine depot injection

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

☐ The patient has had an initial Special Authority approval for paliperidone depot injection or risperidone depot injection

or

☐ The patient has schizophrenia or other psychotic disorder

and

☐ The patient has tried but failed to comply 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

and

☐ The patient has trialled other funded depot antipsychotics (aripiprazole, risperidone, and paliperidone) unless it is considered clinically inappropriate to use these

and

☐ The patient continues to have difficulties with adherence on oral antipsychotic treatments

and

☐ Prescribing clinician has relevant Clinical Director (Mental Health and Addiction services) approval

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

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Aripiprazole

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ The patient has had an initial Special Authority approval for risperidone depot injection, paliperidone depot injection or olanzapine depot injection

or

☐ The patient has schizophrenia or other psychotic disorder

and

☐ The patient has received treatment with oral atypical antipsychotic agents but has been unable to adhere

and

☐ The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in last 12 months

or

☐ Patient has been unable to access olanzapine depot injection due to supply issues with olanzapine depot injection, or otherwise would have been started on olanzapine depot injection but has been unable to due to supply issues with olanzapine depot injection

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.

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

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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

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

☐ The patient has had an initial Special Authority approval for risperidone depot injection or olanzapine depot injection or aripiprazole depot injection

or

☐ The patient has schizophrenia or other psychotic disorder

and

☐ Has been unable to adhere to treatment using oral atypical antipsychotic agents

and

☐ 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

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

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Paliperidone palmitate

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

☐ The patient has schizophrenia

and

☐ The patient has had an initial Special Authority approval for paliperidone once-monthly depot injection

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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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.

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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.

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

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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)

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Phenobarbitone

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ For the treatment of terminal agitation that is unresponsive to other agents

and

☐ The applicant is part of a multidisciplinary team working in palliative care

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

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Melatonin

Initial application
Applications only from a psychiatrist, paediatrician, neurologist, respiratory specialist or any relevant 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 any relevant 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.

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

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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)

- ☐ Patient has genetic documentation of homozygous SMN1 gene deletion, homozygous SMN1 point mutation, or compound heterozygous mutation

and

- ☐ Patient is 18 years of age or under

and

- ☐ Patient has experienced the defined signs and symptoms of SMA type I, II or IIIa prior to three years of age

or

- ☐ Patient is pre-symptomatic

and

- ☐ Patient has three or less copies of SMN2

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)

- ☐ There has been demonstrated maintenance of motor milestone function since treatment initiation

and

- ☐ Patient does not require invasive permanent ventilation (at least 16 hours per day) in the absence of a potentially reversible cause while being treated with nusinersen

and

- ☐ Nusinersen not to be administered in combination other SMA disease modifying treatments or gene therapy

I confirm 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)

- ☐ Patient has genetic documentation of homozygous SMN1 gene deletion, homozygous SMN1 point mutation, or compound heterozygous mutation

and

- ☐ Patient is 18 years of age or under

and

- ☐ Patient has experienced the defined signs and symptoms of SMA type I, II or IIIa prior to three years of age

or

- ☐ Patient is pre-symptomatic

and

- ☐ Patient has three or less copies of SMN2

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)

- ☐ There has been demonstrated maintenance of motor milestone function since treatment initiation

and

- ☐ Patient does not require invasive permanent ventilation (at least 16 hours per day) in the absence of a potentially reversible cause while being treated with risdiplam

and

- ☐ Risdiplam not to be administered in combination other SMA disease modifying treatments or gene therapy

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Lisdexamfetamine dimesilate

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Patient is currently on treatment with lisdexamfetamine dimesilate and met all the following criteria prior to commencing treatment

or

☐ ADHD (Attention Deficit and Hyperactivity Disorder)

and

☐ Diagnosed according to DSM-5 or ICD 11 criteria

and

☐ Applicant is a health practitioner authorised to prescribe treatment consistent with the approval notice gazetted for lisdexamfetamine (see note)

and

☐ Patient is taking a currently subsidised formulation of atomoxetine or methylphenidate hydrochloride (extended-release) for ADHD and has not received sufficient clinical 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

Note: Prescribing practitioner detail is in the relevant approval notice published in the New Zealand Gazette. Approval notices are located through the 'Medicines (controlled drugs) with restrictions under regulation 22 of the Misuse of Drugs Regulations 1977' section of the Medsafe 'Restrictions on the Supply, Prescribing or Administration of Medicines under the Medicines Act 1981 and Misuse of Drugs Regulations 1977' webpage (https://www.medsafe.govt.nz/ of April 2025).

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Dexamfetamine sulfate

Initial application — ADHD in patients aged 5 years or over
Applications from any relevant practitioner. 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 health practitioner authorised to prescribe treatment consistent with the approval notice gazetted for dexamfetamine (see note)

Note: Prescribing practitioner detail is in the relevant approval notice published in the New Zealand Gazette. Approval notices are located through the 'Medicines (controlled drugs) with restrictions under regulation 22 of the Misuse of Drugs Regulations 1977' section of the Medsafe 'Restrictions on the Supply, Prescribing or Administration of Medicines under the Medicines Act 1981 and Misuse of Drugs Regulations 1977' webpage (https://www.medsafe.govt.nz/ of April 2025).

Initial application — ADHD in patients aged under 5 years
Applications from any relevant practitioner. 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

and

- ☐ Applicant is a health practitioner authorised to prescribe treatment consistent with the approval notice gazetted for dexamfetamine (see note)

Note: Prescribing practitioner detail is in the relevant approval notice published in the New Zealand Gazette. Approval notices are located through the 'Medicines (controlled drugs) with restrictions under regulation 22 of the Misuse of Drugs Regulations 1977' section of the Medsafe 'Restrictions on the Supply, Prescribing or Administration of Medicines under the Medicines Act 1981 and Misuse of Drugs Regulations 1977' webpage (https://www.medsafe.govt.nz/ of April 2025).

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

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Methylphenidate hydrochloride (Rubifen; Rubifen SR; Ritalin; Methylphenidate ER - Teva; Methylphenidate Sandoz XR; Rubifen LA)

Initial application — ADHD in patients aged 5 years or over
Applications from any relevant practitioner. 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 health practitioner authorised to prescribe treatment consistent with the approval notice gazetted for methylphenidate (see note)

Note: Prescribing practitioner detail is in the relevant approval notice published in the New Zealand Gazette. Approval notices are located through the 'Medicines (controlled drugs) with restrictions under regulation 22 of the Misuse of Drugs Regulations 1977' section of the Medsafe 'Restrictions on the Supply, Prescribing or Administration of Medicines under the Medicines Act 1981 and Misuse of Drugs Regulations 1977' webpage (https://www.medsafe.govt.nz/ of April 2025).

Initial application — ADHD in patients aged under 5 years
Applications from any relevant practitioner. 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
and
☐ Applicant is a health practitioner authorised to prescribe treatment consistent with the approval notice gazetted for methylphenidate (see note)

Note: Prescribing practitioner detail is in the relevant approval notice published in the New Zealand Gazette. Approval notices are located through the 'Medicines (controlled drugs) with restrictions under regulation 22 of the Misuse of Drugs Regulations 1977' section of the Medsafe 'Restrictions on the Supply, Prescribing or Administration of Medicines under the Medicines Act 1981 and Misuse of Drugs Regulations 1977' webpage (https://www.medsafe.govt.nz/ of April 2025).

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, Methylphenidate Sandoz XR or Rubifen LA.

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 Extended Release (Concerta; Ritalin LA)

Initial application — ADHD
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ ADHD (Attention Deficit and Hyperactivity Disorder)
- **and** ☐ Diagnosed according to DSM-IV or ICD 10 criteria
- **and** ☐ Applicant is a health practitioner authorised to prescribe treatment consistent with the approval notice gazetted for methylphenidate (see note)
- **and**
  - ☐ 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
  - **or** ☐ There is significant concern regarding the risk of diversion or abuse of immediate-release methylphenidate hydrochloride

or

- ☐ Patient meets the Special Authority criteria for SA2590 methylphenidate hydrochloride
- **and** ☐ Patient is unable to access other methylphenidate hydrochloride presentations under Special Authority criteria SA2590 due to an out of stock (see note)

Note: Criterion 2 is to permit short-term funding to cover an out-of-stock on tab extended-release Methylphenidate ER – Teva and tab sustained-release 20 mg Rubifen SR subsidised under SA2590 (https://schedule.pharmac.govt.nz/latest/SA2590.pdf).
Prescribing practitioner detail is in the relevant approval notice published in the New Zealand Gazette. Approval notices are located through the 'Medicines (controlled drugs) with restrictions under regulation 22 of the Misuse of Drugs Regulations 1977' section of the Medsafe 'Restrictions on the Supply, Prescribing or Administration of Medicines under the Medicines Act 1981 and Misuse of Drugs Regulations 1977' webpage (https://www.medsafe.govt.nz/ of April 2025).

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 Concerta or Ritalin LA.

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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)

☐ The patient has a diagnosis of narcolepsy and has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more

and

☐ The patient has a multiple sleep latency test with a mean sleep latency of less than or equal to 10 minutes and 2 or more sleep onset rapid eye movement periods

or

☐ The patient has at least one of: cataplexy, sleep paralysis or hypnagogic hallucinations

and

☐ An effective dose of a subsidised formulation of methylphenidate or dexamfetamine has been trialled and discontinued because of intolerable side effects

or

☐ Methylphenidate and dexamfetamine are contraindicated

or

☐ Patient meets the Special Authority criteria for methylphenidate hydrochloride or methylphenidate hydrochloride extended-release for narcolepsy

and

☐ Patient is unable to access methylphenidate hydrochloride presentations due to an out of stock (see note)

Note: Criterion 2 is to permit short-term funding to cover an out-of-stock of methylphenidate hydrochloride or methylphenidate hydrochloride extended release.

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

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
Reg No:	First Names:	First Names: .....
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Rivastigmine patches

Initial application
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has been diagnosed with dementia

and

- ☐ The patient is contraindicated to or has experienced intolerable side effects from donepezil tablets

Renewal

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

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

- ☐ The treatment remains appropriate

and

- ☐ 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)

- ☐ Patient is currently enrolled in a recognised comprehensive treatment programme for alcohol dependence

and

- ☐ 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)

- ☐ Compliance with the medication (prescriber determined)

and

- ☐ Patient is still unstable and requires further treatment

or

- ☐ Patient achieved significant improvement but requires further treatment

or

- ☐ Patient is well controlled but requires maintenance therapy

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

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APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA1845
October 2026

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

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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)

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

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Buprenorphine with naloxone

Initial application — Detoxification
Applications from any medical practitioner. Approvals valid for 6 weeks.
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 6 weeks.
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

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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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)

- ☐ Patient is or has been receiving maintenance therapy with buprenorphine with naloxone (and is not receiving methadone)

and

- ☐ Patient is currently enrolled in an opioid substitution program in a service approved by the Ministry of Health

and

- ☐ 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)

- ☐ Patient received but failed detoxification with buprenorphine with naloxone

and

- ☐ Maintenance therapy with buprenorphine with naloxone is planned (and patient will not be receiving methadone)

and

- ☐ Patient is currently enrolled in an opioid substitution program in a 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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Oncology Agents and Immunosuppressants

APPLICANT (stamp or sticker acceptable)

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^2 on days 1 and 2 every 4 weeks for a maximum of 6 cycles

Note: Indication marked with a * includes indications that are unapproved. 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL).

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.

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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)

- ☐ Patient is refractory to or has relapsed within 12 months of rituximab in combination with bendamustine
- **and**
- ☐ Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles

or

- ☐ Patients have not received a bendamustine regimen within the last 12 months
- **and**
  - ☐ Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+)
  - **and**
  - ☐ Patient has had a rituximab treatment-free interval of 12 months or more
  - **or**
  - ☐ Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients

Note: 'indolent, low-grade lymphomas' includes follicular, mantle cell, marginal zone and lymphoplasmacytic/ 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)

- ☐ Patient has Hodgkin's lymphoma requiring treatment
- **and**
- ☐ Patient has a ECOG performance status of 0-2
- **and**
- ☐ Patient has received one prior line of chemotherapy
- **and**
- ☐ Patient's disease relapsed or was refractory following prior chemotherapy
- **and**
- ☐ Bendamustine is to be administered in combination with gemcitabine and vinorelbine (BeGeV) at a maximum dose of no greater than 90 mg/m2 twice per cycle, for a maximum of four cycles

Note: Indications marked with * are unapproved indications.

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

- ☐ The individual has intermediate or high risk MDS based on an internationally recognised scoring system

or

- ☐ The individual has chronic myelomonocytic leukaemia (based on an intermediate or high risk score from an internationally recognised scoring system or 10%-29% marrow blasts without myeloproliferative disorder)

or

- ☐ The individual has acute myeloid leukaemia according to World Health Organisation Classification (WHO)

and

- ☐ The individual has an estimated life expectancy of at least 3 months

Renewal

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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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.

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

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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^2 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)

☐ No evidence of disease progression

and

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

Initial application — Neuroblastoma

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

Prerequisites(tick box where appropriate)

☐ The patient has neuroblastoma

Renewal — Neuroblastoma

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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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

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

☐ The patient has Waldenström Macroglobulinaemia/Lymphoplasmacytic Lymphoma requiring treatment
and
☐ The patient has not received prior bortezomib treatment

Renewal — Waldenström Macroglobulinaemia

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 clinical disease progression during bortezomib use

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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 15 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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Venetoclax

Initial application — previously untreated chronic lymphocytic leukaemia in combination with obinutuzumab
Applications from any relevant practitioner. Approvals valid for 15 months.
Prerequisites(tick boxes where appropriate)

☐ Individual is currently on treatment with venetoclax and obinutuzumab and met all of the following criteria prior to commencing treatment

or

☐ Individual has previously untreated chronic lymphocytic leukaemia

and

☐ Venetoclax is to be administered with obinutuzumab

and

☐ Venetoclax is to be used to a maximum dose of 400 mg and for a total of 12 (28 day) cycles

Initial application — previously untreated chronic lymphocytic leukaemia in combination with ibrutinib
Applications from any relevant practitioner. Approvals valid for 15 months.
Prerequisites(tick boxes where appropriate)

☐ Individual is currently on treatment with venetoclax and/or ibrutinib and met all of the following criteria prior to commencing treatment

or

☐ Individual has previously untreated chronic lymphocytic leukaemia

and

☐ Venetoclax is to be administered in combination with ibrutinib

and

☐ Venetoclax is to be used to a maximum dose of 400 mg and for a total of 12 (28 day) cycles

Initial application — relapsed/refractory chronic lymphocytic leukaemia
Applications from any relevant practitioner. Approvals valid for 8 months.
Prerequisites(tick boxes where appropriate)

☐ Individual has chronic lymphocytic leukaemia requiring treatment

and

☐ Individual has received at least one prior therapy for chronic lymphocytic leukaemia

and

☐ The individual's disease has relapsed

and

☐ Venetoclax to be used in combination with six 28-day cycles of rituximab commencing after the 5-week dose titration schedule with venetoclax

and

☐ Individual has an ECOG performance status of 0-2

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)

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Venetoclax *- continued*

Renewal — relapsed/refractory chronic lymphocytic leukaemia

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

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

Prerequisites(tick boxes where appropriate)

☐ Treatment remains clinically appropriate and the individual is benefitting from and tolerating treatment

and

☐ Venetoclax is to be discontinued after a maximum of 24 months of treatment following the titration schedule unless earlier discontinuation is required due to disease progression or unacceptable toxicity

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL) and B-cell prolymphocytic leukaemia (B-PLL)*. Indications marked with * are Unapproved indications.

Initial application — previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*

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

Prerequisites(tick boxes where appropriate)

☐ Individual has previously untreated chronic lymphocytic leukaemia

and

☐ There is documentation confirming that individual has 17p deletion by FISH testing or TP53 mutation by sequencing

and

☐ Individual 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 from any relevant practitioner. 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

Initial application — previously untreated acute myeloid leukaemia

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

Prerequisites(tick boxes where appropriate)

☐ The individual is currently on treatment with venetoclax and met all remaining special authority criteria prior to commencing treatment

or

☐ Individual has previously untreated acute myeloid leukaemia (see note a), according to World Health Organization (WHO) Classification

and

☐ Venetoclax not to be used in combination with standard intensive remission induction chemotherapy

and

☐ Venetoclax to be used in combination with azacitidine or low dose cytarabine

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

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Venetoclax *- continued*

Renewal — previously untreated acute myeloid leukaemia

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

Note:

a) 'Acute myeloid leukaemia' includes myeloid sarcoma*

b) 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: .....

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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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)

- ☐ Treatment remains clinically appropriate and patient is benefitting from treatment

and

- ☐ No evidence of progressive disease

or

- ☐ Evidence of residual (not progressive) disease and the patient would continue to benefit from treatment in the clinician's opinion

and

- ☐ Treatment to be administered as maintenance treatment

and

- ☐ Treatment not to be administered in combination with other chemotherapy

and

- ☐ Patient has received one line** of previous treatment with platinum-based chemotherapy

and

- ☐ Documentation confirming that the patient has been informed and acknowledges that the funded treatment period of olaparib will not be continued beyond 2 years if the patient experiences a complete response to treatment and there is no radiological evidence of disease at 2 years

or

- ☐ Patient has received at least two lines** of previous treatment with platinum-based chemotherapy

Note: *Note "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component.
**A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

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Ibrutinib

Initial application — previously untreated chronic lymphocytic leukaemia in combination with venetoclax
Applications from any relevant practitioner. Approvals valid for 15 months.
Prerequisites(tick boxes where appropriate)

☐ Individual is currently on treatment with ibrutinib and/or venetoclax and met all of the following criteria prior to commencing treatment

or

☐ Individual has previously untreated CLL

and

☐ Ibrutinib is to be administered at a maximum dose of 420 mg daily for 3 (28 day) cycles as monotherapy, followed by a maximum of 12 (28 day) cycles in combination with venetoclax

Initial application — chronic lymphocytic leukaemia (CLL)
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Individual has chronic lymphocytic leukaemia (CLL) requiring therapy

and

☐ Ibrutinib is to be used as monotherapy

and

☐ Individual has experienced intolerable side effects, or their disease has relapsed or is refractory following at least one prior line of therapy

and

☐ Individual has not received ibrutinib monotherapy previously

Renewal — chronic lymphocytic leukaemia (CLL)

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

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

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

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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

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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)

☐ Patient has relapsed or refractory plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment

and

☐ Patient has not received prior funded pomalidomide

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)

- ☐ The patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis or accelerated phase

or

- ☐ The patient has a diagnosis of Philadelphia chromosome-positive acute lymphoid leukaemia (Ph+ ALL)

or

- ☐ The patient has a diagnosis of CML in chronic phase

and

- ☐ Patient has documented treatment failure* with imatinib

or

- ☐ Patient has experienced treatment-limiting toxicity with imatinib precluding further treatment with imatinib

or

- ☐ Patient has high-risk chronic-phase CML defined by the Sokal or EURO scoring system

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)

- ☐ Lack of treatment failure while on dasatinib*

and

- ☐ Dasatinib treatment remains appropriate and the patient is benefiting from treatment

Note: *treatment failure for CML as defined by Leukaemia Net Guidelines.

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

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Erlotinib

Initial application
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC)

and

☐ There is documentation confirming that the disease expresses activating mutations of EGFR

and

☐ Patient is treatment naive

or

☐ Patient has received prior treatment in the adjuvant setting and/or while awaiting EGFR results

or

☐ The patient has discontinued osimertinib or gefitinib due to intolerance

and

☐ 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

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

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Sunitinib

Initial application — RCC
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has metastatic renal cell carcinoma

and

- ☐ The patient has not previously received funded sunitinib

Renewal — RCC

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

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

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 is clinically benefiting from treatment and continued treatment remains appropriate

and

- ☐ Sunitinib is to be discontinued at disease progression

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.

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Pazopanib

Initial application

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 patient has metastatic renal cell carcinoma of predominantly clear cell histology

and

☐ The patient is treatment naive

or

☐ The patient has only received prior cytokine treatment

and

☐ The patient has an ECOG performance score of 0-2

and

The patient has intermediate or poor prognosis defined as:

☐ Lactate dehydrogenase level > 1.5 times upper limit of normal

or

☐ Haemoglobin level < lower limit of normal

or

☐ Corrected serum calcium level > 10 mg/dL (2.5 mmol/L)

or

☐ Interval of < 1 year from original diagnosis to the start of systemic therapy

or

☐ Karnofsky performance score of less than or equal to 70

or

☐ 2 or more sites of organ metastasis

and

☐ Pazopanib to be used for a maximum of 3 months

or

☐ The patient has metastatic renal cell carcinoma

and

☐ The patient has discontinued sunitinib within 3 months of starting treatment due to intolerance

and

☐ The cancer did not progress whilst on sunitinib

and

☐ Pazopanib to be used for a maximum of 3 months

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 3 months.

Prerequisites(tick box where appropriate)

☐ There is no evidence of disease progression

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Gefitinib

Initial application
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC)

and

☐ Patient is treatment naive

or

☐ Patient has received prior treatment in the adjuvant setting and/or while awaiting EGFR results

or

☐ The patient has discontinued osimertinib or erlotinib due to intolerance

and

☐ The cancer did not progress whilst on osimertinib or erlotinib

and

☐ There is documentation confirming that disease expresses activating mutations of EGFR

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)

- ☐ Patient has locally advanced, or metastatic, unresectable, non-small cell lung cancer

and

- ☐ There is documentation confirming that the patient has an ALK tyrosine kinase gene rearrangement using an appropriate ALK test

and

- ☐ Patient has an ECOG performance score of 0-2

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)

- ☐ No evidence of progressive disease according to RECIST criteria

and

- ☐ 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

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

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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

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

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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
- **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

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

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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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 supressed

and

☐ Patient is not a candidate for radiotherapy with curative intent

and

☐ Surgery is clinically inappropriate

and

☐ Patient has an ECOG performance status of 0-2

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

or

- ☐ Patient has experienced treatment-limiting toxicity from treatment with atezolizumab with bevacizumab

and

- ☐ No disease progression since initiation of atezolizumab with bevacizumab

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

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Lenvatinib *- continued*

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

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)

☐ Patient is currently on treatment with osimertinib and met all remaining criteria prior to commencing treatment

or

☐ Patient has locally advanced or metastatic, incurable, non-squamous non-small cell lung cancer (NSCLC)

and

☐ Patient is treatment naïve

or

☐ Patient has received prior chemotherapy in the adjuvant setting and/or while awaiting EGFR results

or

☐ The patient has discontinued gefitinib or erlotinib due to intolerance

and

☐ The cancer did not progress while on gefitinib or erlotinib

and

☐ There is documentation confirming that the cancer expresses activating mutations of EGFR

and

☐ Patient has an ECOG performance status 0-3

and

☐ Baseline measurement of overall tumour burden is documented clinically and radiologically

Renewal — NSCLC – first line

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

Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick box where appropriate)

☐ Response to or stable disease with treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

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

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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)

☐ Patient is currently on treatment with osimertinib and met all remaining criteria prior to commencing treatment

or

☐ Patient has locally advanced or metastatic, incurable, non-squamous non-small cell lung cancer (NSCLC)

and

☐ Patient has an ECOG performance status 0-3

and

☐ The patient must have received previous treatment with erlotinib or gefitinib

and

☐ There is documentation confirming that the cancer expresses T790M mutation of EGFR following progression on or after erlotinib or gefitinib

and

☐ The treatment must be given as monotherapy

and

☐ Baseline measurement of overall tumour burden is documented clinically and radiologically

Renewal — NSCLC – second line

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

Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick box where appropriate)

☐ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

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Axitinib

Initial application
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 ECOG performance status of 0-2

Renewal

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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Crizotinib

Initial application
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Individual has locally advanced or metastatic, unresectable, non-squamous non-small cell lung cancer

and

☐ The individual has not received entrectinib

or

☐ The individual has received an initial Special Authority approval for entrectinib and has discontinued entrectinib due to intolerance

and

☐ The cancer did not progress while the individual was on entrectinib

and

☐ There is documentation confirming that the patient has a ROS1 rearrangement using an appropriate ROS1 test

and

☐ Individual has ECOG performance score of 0-3

and

☐ Baseline measurement of overall tumour burden is documented clinically and radiologically

Renewal

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

Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Response to treatment has been determined by comparable radiological assessment following the most recent treatment period

and

☐ No evidence of disease progression

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Dabrafenib

Initial application — stage III or IV resected melanoma - adjuvant
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a)

or

☐ The individual has received neoadjuvant treatment with a PD-1/PD-L1 inhibitor

and

☐ Adjuvant treatment with dabrafenib is required

and

☐ The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma

and

☐ Treatment must be adjuvant to complete surgical resection

and

☐ Treatment must be initiated within 13 weeks of surgical resection, unless delay is necessary due to post-surgery recovery (see note b)

and

☐ The individual has a confirmed BRAF mutation

and

☐ Dabrafenib must be administered in combination with trametinib

and

☐ The individual has ECOG performance score 0-2

Note:

a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition

b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)

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

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

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Dabrafenib *- continued*

Renewal — stage III or IV resected melanoma - adjuvant

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

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

Prerequisites(tick boxes where appropriate)

- ☐ No evidence of disease recurrence
- **and**
- ☐ Dabrafenib must be administered in combination with trametinib
- **and**
- ☐ Treatment to be discontinued at signs of disease recurrence or at completion of 12 months' total treatment course, including any systemic neoadjuvant treatment

or

- ☐ The individual has received adjuvant treatment with a BRAF/MEK inhibitor
- **and**
- ☐ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV
- **and**
- ☐ The individual meets initial application criteria for dabrafenib for unresectable or metastatic melanoma

or

- ☐ The individual has received adjuvant treatment with a BRAF/MEK inhibitor
- **and**
- ☐ The individual has received a BRAF/MEK inhibitor for unresectable or metastatic melanoma
- **and**
- ☐ The individual meets renewal criteria for dabrafenib for unresectable or metastatic melanoma

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

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Dabrafenib *- continued*

Initial application — unresectable or metastatic melanoma
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV
- **and** ☐ Baseline measurement of overall tumour burden is documented clinically and radiologically
- **and** ☐ The individual has ECOG performance score 0-2
- **and** ☐ The individual has confirmed BRAF mutation
- **and** ☐ Dabrafenib must be administered in combination with trametinib
- **and**
  - ☐ The individual has been diagnosed in the metastatic or unresectable stage III or IV setting
  - **or** ☐ The individual did not receive treatment in the adjuvant setting with a BRAF/MEK inhibitor
  - **or**
    - ☐ The individual received treatment in the adjuvant setting with a BRAF/MEK inhibitor
    - **and** ☐ The individual did not experience disease recurrence while on treatment with that BRAF/MEK inhibitor
    - **and** ☐ The individual did not experience disease recurrence within six months of completing adjuvant treatment with a BRAF/MEK inhibitor

Renewal — unresectable or metastatic melanoma

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

Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ The individual's disease has had a complete response to treatment
- **or** ☐ The individual's disease has had a partial response to treatment
- **or** ☐ The individual has stable disease with treatment
- **and** ☐ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

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

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Trametinib

Initial application — stage III or IV resected melanoma - adjuvant
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a)

or

☐ The individual has received neoadjuvant treatment with a PD-1/PD-L1 inhibitor

and

☐ Adjuvant treatment with trametinib is required

and

☐ The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma

and

☐ Treatment must be adjuvant to complete surgical resection

and

☐ Treatment must be initiated within 13 weeks of surgical resection, unless delay is necessary due to post-surgery recovery (see note b)

and

☐ The individual has a confirmed BRAF mutation

and

☐ Trametinib must be administered in combination with dabrafenib

and

☐ The individual has ECOG performance score 0-2

Note:

a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition

b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)

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

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Trametinib *- continued*

Renewal — stage III or IV resected melanoma - adjuvant

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

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

Prerequisites(tick boxes where appropriate)

☐ No evidence of disease recurrence
and
☐ Trametinib must be administered in combination with dabrafenib
and
☐ Treatment to be discontinued at signs of disease recurrence or at completion of 12 months' total treatment course, including any systemic neoadjuvant treatment

or

☐ The individual has received adjuvant treatment with a BRAF/MEK inhibitor
and
☐ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV
and
☐ The individual meets initial application criteria for trametinib for unresectable or metastatic melanoma

or

☐ The individual has received adjuvant treatment with a BRAF/MEK inhibitor
and
☐ The individual has received a BRAF/MEK inhibitor for unresectable or metastatic melanoma
and
☐ The individual meets renewal criteria for trametinib for unresectable or metastatic melanoma

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

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Trametinib *- continued*

Initial application — unresectable or metastatic melanoma
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ The individual has metastatic or unresectable melanoma (excluding uveal melanoma) stage III or IV

and

- ☐ Baseline measurement of overall tumour burden is documented clinically and radiologically

and

- ☐ The individual has ECOG performance score 0-2

and

- ☐ The individual has confirmed BRAF mutation

and

- ☐ Trametinib must be administered in combination with dabrafenib

and

- ☐ The individual has been diagnosed in the metastatic or unresectable stage III or IV setting

or

- ☐ The individual did not receive treatment in the adjuvant setting with a BRAF/MEK inhibitor

or

- ☐ The individual received treatment in the adjuvant setting with a BRAF/MEK inhibitor

and

- ☐ The individual did not experience disease recurrence while on treatment with that BRAF/MEK inhibitor

and

- ☐ The individual did not experience disease recurrence within six months of completing adjuvant treatment with a BRAF/MEK inhibitor

Renewal — unresectable or metastatic melanoma

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

Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ The individual's disease has had a complete response to treatment

or

- ☐ The individual's disease has had a partial response to treatment

or

- ☐ The individual has stable disease with treatment

and

- ☐ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

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Entrectinib

Initial application
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Individual has locally advanced or metastatic, unresectable, non-squamous non-small cell lung cancer

and

☐ The individual has not received crizotinib

or

☐ The individual has received an initial Special Authority approval for crizotinib and has discontinued crizotinib due to intolerance

and

☐ The cancer did not progress while the individual was on crizotinib

and

☐ There is documentation confirming that the patient has a ROS1 rearrangement using an appropriate ROS1 test

and

☐ Individual has ECOG performance score of 0-3

and

☐ Baseline measurement of overall tumour burden is documented clinically and radiologicallyy

Renewal

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

Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Response to treatment has been determined by comparable radiological assessment following the most recent treatment period

and

☐ No evidence of disease progression

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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)

- ☐ The patient is clinically benefiting from treatment and continued treatment remains appropriate

and

- ☐ Abiraterone acetate to be discontinued at progression

and

- ☐ No initiation of taxane chemotherapy with abiraterone

and

- ☐ The regular 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.

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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)

- ☐ Patient has oestrogen-receptor positive locally advanced or metastatic breast cancer

and

- ☐ Patient has disease progression following prior treatment with an aromatase inhibitor or tamoxifen for their locally advanced or metastatic disease

and

- ☐ Treatment to be given at a dose of 500 mg monthly following loading doses

and

- ☐ Treatment to be discontinued at disease progression

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)

- ☐ Treatment remains appropriate and patient is benefitting from treatment

and

- ☐ Treatment to be given at a dose of 500 mg monthly

and

- ☐ There is no evidence of disease progression

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Long-acting Somatostatin Analogues

Initial application — Malignant Bowel Obstruction
Applications from any relevant practitioner. Approvals valid for 2 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has nausea* and vomiting* due to malignant bowel obstruction*

and

- ☐ Treatment with antiemetics, rehydration, antimuscarinic agents, corticosteroids and analgesics for at least 48 hours has not been successful

and

- ☐ Treatment to be given for up to 4 weeks

Note: Indications marked with * are unapproved indications.

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 from any relevant practitioner. Approvals valid for 3 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has acromegaly

and

- ☐ Treatment with surgery and radiotherapy is not suitable or was unsuccessful

or

- ☐ Treatment is for an interim period while awaiting the beneficial effects of radiotherapy

and

- ☐ Treatment with a dopamine agonist has been unsuccessful

Renewal — Acromegaly

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

Applications from any relevant practitioner. Approvals valid for 2 years.
Prerequisites(tick box where appropriate)

- ☐ IGF1 levels have decreased since starting treatment

Note: In patients with acromegaly, treatment should be discontinued if IGF1 levels have not decreased 3 months after treatment. In patients treated with radiotherapy treatment should be withdrawn every 2 years, for 1 month, for assessment of remission. Treatment should be stopped where there is biochemical evidence of remission (normal IGF1 levels) following treatment withdrawal for at least 4 weeks

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

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Long-acting Somatostatin Analogues *- continued*

Initial application — pre-operative acromegaly
Applications from any relevant practitioner. 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

Initial application — Other Indications
Applications from any relevant practitioner. 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**
- ☐ Surgery has been unsuccessful
- **or**
- ☐ Patient has metastatic disease after treatment with H2 antagonist or proton pump inhibitors has been unsuccessful
- **or**
- ☐ Insulinomas
- **and**
- ☐ Surgery is contraindicated or has not been successful
- **or**
- ☐ For pre-operative control of hypoglycaemia and for maintenance therapy
- **or**
- ☐ Carcinoid syndrome (diagnosed by tissue pathology and/or urinary 5HIAA analysis)
- **and**
- ☐ Disabling symptoms not controlled by maximal medical therapy

Note: The use of a long-acting somatostatin analogue in patients with fistulae, oesophageal varices, miscellaneous diarrhoea and hypotension will not be funded under Special Authority

Renewal — Other Indications

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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SA2619 - Etanercept

Plaque psoriasis - Initial application 232
Plaque psoriasis - Renewal 233
Stills disease - adult-onset (AOSD) - Initial application 226
Ankylosing spondylitis - Initial application 227
Ankylosing spondylitis - Renewal 227
Arthritis - oligoarticular course juvenile idiopathic - Initial application 228
Arthritis - oligoarticular course juvenile idiopathic - Renewal 229
Arthritis - polyarticular course juvenile idiopathic - Initial application 228
Arthritis - polyarticular course juvenile idiopathic - Renewal 228
Arthritis - psoriatic - Initial application 229
Arthritis - psoriatic - Renewal 230
Arthritis - rheumatoid - Initial application 231
Arthritis - rheumatoid - Renewal 231
Pyoderma gangrenosum* - Initial application 230
Undifferentiated spondyloarthritis* - Initial application 234
Undifferentiated spondyloarthritis* - Renewal 234

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Etanercept

Initial application — Stills disease - adult-onset (AOSD)
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has had a Special Authority approval for adalimumab or tocilizumab for AOSD

and

- ☐ Patient has experienced intolerable side effects

or

- ☐ Patient has received insufficient benefit to meet the renewal criteria from at least a 3-month trial of adalimumab or tocilizumab

or

- ☐ Patient diagnosed with AOSD according to the Yamaguchi criteria

and

- ☐ Patient has tried and received insufficient benefit from at least 6 months of corticosteroids at a dose of at least 0.5 mg/kg prednisone-equivalents, NSAIDs and methotrexate, unless contraindicated

and

- ☐ Patient has persistent symptoms of disabling poorly controlled and active disease

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Etanercept *- continued*

Initial application — ankylosing spondylitis
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has had a Special Authority approval for adalimumab for ankylosing spondylitis

and

☐ Patient has experienced intolerable side effects

or

☐ Patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis

or

☐ Patient has a confirmed diagnosis of ankylosing spondylitis

and

☐ Patient has low back pain and stiffness that is relieved by exercise but not by rest

and

☐ Patient has bilateral sacroiliitis demonstrated by radiologic imaging

and

☐ Disease has not responded adequately to treatment with two or more NSAIDs (unless contraindicated), 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

☐ BASDAI of at least 6 on a 10-point scale completed after 3-month exercise trial before ceasing any previous pharmacological treatment and not more than 1 month before the application

Renewal — ankylosing spondylitis

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

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

☐ BASDAI has improved from pre-treatment baseline either by at least 4 points on a 10-point scale, or by at least 50%

and

☐ Maximum dose 50 mg every 7 days

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Etanercept *- continued*

Initial application — arthritis - polyarticular course juvenile idiopathic
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has had a Special Authority approval for adalimumab 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

☐ At least 5 active joints and at least 3 joints with pain, tenderness or a limited range of motion, after a 3-month trial of methotrexate at the maximum tolerated dose, unless contraindicated

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, unless contraindicated

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, at least a 50% decrease in active joint count from baseline

or

☐ On subsequent reapplications, at least a continuing 30% improvement in active joint count from baseline

Initial application — arthritis - oligoarticular course juvenile idiopathic
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has had a Special Authority approval for adalimumab 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

☐ At least 2 active joints with pain, tenderness or a limited range of motion, after a 3-month trial of methotrexate at the maximum tolerated dose, unless contraindicated

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, unless contraindicated

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Etanercept *- continued*

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, at least a 50% decrease in active joint count from baseline

or

- ☐ On subsequent reapplications, at least a continuing 30% improvement in active joint count from baseline

Initial application — arthritis - psoriatic

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

Prerequisites(tick boxes where appropriate)

- ☐ Patient has had a Special Authority approval for adalimumab or secukinumab for psoriatic arthritis

and

- ☐ Patient has experienced intolerable side effects

or

- ☐ Patient has received insufficient benefit to meet the renewal criteria for psoriatic arthritis

or

- ☐ Patient has received insufficient benefit from at least 3 months of methotrexate at maximum tolerated dose unless contraindicated

and

- ☐ Patient received insufficient benefit from at least 3 months of sulfasalazine or leflunomide at maximum tolerated dose unless contraindicated

and

- ☐ Patient has persistent symptoms of poorly controlled and active disease in at least 15 joints

or

- ☐ Patient has persistent symptoms of poorly controlled and active disease in at least 4 joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

- ☐ Patient has a CRP greater than 15 mg/L measured within one month before the application

or

- ☐ Patient has an ESR greater than 25 mm per hour measured within one month before the application

or

- ☐ ESR and CRP not measured as patient is receiving prednisone therapy greater than 5 mg per day received for more than 3 months

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Etanercept *- continued*

Renewal — arthritis - psoriatic

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

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

Prerequisites(tick boxes where appropriate)

- ☐ Following initial treatment, at least a 50% decrease in active joint count from baseline

or

- ☐ At least a continuing 30% improvement in active joint count from baseline

and

- ☐ Maximum dose 50 mg every 7 days

Initial application — pyoderma gangrenosum*

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

Prerequisites(tick boxes where appropriate)

- ☐ Patient has received insufficient benefit from 3 months of conventional therapy including a minimum of 3 pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate). Where conventional pharmaceuticals are contraindicated, a 3 month trial has occurred of those that are not contraindicated

and

- ☐ Maximum of 8 doses every 4 months

Note: Indications marked with * are unapproved indications.

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Etanercept *- continued*

Initial application — arthritis - rheumatoid
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has had a Special Authority approval for adalimumab for rheumatoid arthritis

and

☐ Patient has experienced intolerable side effects

or

☐ Patient has received insufficient benefit to meet the renewal criteria for rheumatoid arthritis

or

☐ Patient has had rheumatoid arthritis (either confirmed by radiologic imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive)

and

☐ Patient has received insufficient benefit from at least 3 months of methotrexate at a maximum tolerated dose (unless contraindicated)

and

☐ Patient has received insufficient benefit from at least 3 months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses unless contraindicated)

and

☐ Patient has received insufficient benefit from at least 3 months of methotrexate in combination with the maximum tolerated dose of ciclosporin, unless contraindicated

or

☐ Patient has received insufficient benefit from at least 3 months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate, unless contraindicated

and

☐ Patient has persistent symptoms of poorly controlled and active disease in at least 15 joints

or

☐ Patient has persistent symptoms of poorly controlled and active disease in at least 4 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, at least a 50% decrease in active joint count from baseline

or

☐ On subsequent reapplications, at least a continuing 30% improvement in active joint count from baseline

and

☐ Maximum dose 50 mg every 7 days

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Etanercept *- continued*

Initial application — Plaque psoriasis
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has had a Special Authority approval for adalimumab for plaque psoriasis

and

☐ Patient has experienced intolerable side effects

or

☐ Patient has received insufficient benefit to meet the renewal criteria for plaque psoriasis

or

☐ Patient has "whole body" plaque psoriasis with a PASI score of greater than 10

or

☐ Patient has plaque psoriasis of the face, or palm of a hand or sole of a foot

or

☐ Patient has localised genital or flexural plaque psoriasis with a DLQI score greater than 10

and

☐ Patient has received insufficient benefit from (see Note), or has experienced intolerable side effects from, at least 3 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 the most recent prior treatment course within 1 month of stopping that treatment

and

☐ The most recent PASI or DLQI assessment is within 1 month before the application

Note: "Insufficient benefit " is defined as: for whole body plaque psoriasis, a PASI score of greater than 10, for 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 — Plaque psoriasis

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

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

Prerequisites(tick boxes where appropriate)

☐ Patient had "whole body" plaque psoriasis at the start of treatment

and

☐ Patient has a PASI score which is reduced by 75% or more, or is sustained at this level, compared with the pre-treatment baseline

or

☐ Patient has a DLQI improvement of 5 or more, compared with the pre-treatment baseline

or

☐ Patient had plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment

and

☐ 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, compared to the pre-treatment baseline

or

☐ Patient has a reduction of 75% or more in the skin area affected, or sustained at this level, compared to the pre-treatment baseline

or

☐ Patient has localised genital or flexural plaque psoriasis at the start of treatment

and

☐ Patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, compared to the pre-treatment baseline

or

☐ Patient has a DLQI improvement of 5 or more, compared to the pre-treatment baseline

and

☐ Maximum dose 50 mg every 7 days

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Etanercept *- continued*

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

☐ Patient has undifferentiated peripheral spondyloarthritis with active peripheral joint arthritis in at least 4 joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

☐ Patient has received insufficient benefit from least 3 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 within one month before the application

or

☐ Patient has an ESR greater than 25 mm per hour measured within one month before the application

or

☐ ESR and CRP not measured as patient is currently receiving prednisone therapy greater than 5 mg per day received for more than 3 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 experienced at least a 50% decrease in active joint count from baseline

or

☐ Patient has experienced at least a continuing 30% improvement in active joint count from baseline

and

☐ Maximum dose 50 mg every 7 days

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)

Initial application — arthritis - rheumatoid - TNF inhibitors contraindicated
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ Treatment with a Tumour Necrosis Factor alpha inhibitor is contraindicated

and

- ☐ Patient has had rheumatoid arthritis (either confirmed by radiologic imaging, or the patient is CCP antibody positive)

and

- ☐ Disease has not responded to at least 3 months of methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose, unless contraindicated

and

- ☐ Disease has not responded to at least 3 months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses), unless contraindicated

and

- ☐ Disease has not responded to at least 3 months of methotrexate in combination with the maximum tolerated dose of ciclosporin, unless contraindicated

or

- ☐ Disease has not responded to at least 3 months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate, unless contraindicated

and

- ☐ Patient has persistent symptoms of poorly controlled and active disease in at least 20 joints

or

- ☐ Patient has persistent symptoms of poorly controlled and active disease in at least 4 joints from the following: wrist, elbow, knee, ankle, shoulder, or hip

and

- ☐ Patient has CRP greater than 15 mg/L measured within one month before the application

or

- ☐ CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day received for more than 3 months

and

- ☐ Maximum of two 1000 mg infusions given two weeks apart

Initial application — arthritis - rheumatoid - prior TNF inhibitor use
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has had a Special Authority approval for etanercept or adalimumab for rheumatoid arthritis

and

- ☐ Patient has experienced intolerable side effects

or

- ☐ Following at least a 4 month trial of adalimumab or etanercept, the renewal criteria for rheumatoid arthritis were not met

and

- ☐ Maximum of two 1000 mg infusions 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 — arthritis - rheumatoid - re-treatment for people who have experienced a partial response to rituximab

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

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

Prerequisites(tick boxes where appropriate)

- ☐ Following the initial course of rituximab the patient experienced between a 30% and 50% decrease in active joint count from baseline

or

- ☐ Following the second course of rituximab the patient experienced at least a 50% decrease in active joint count from baseline

or

- ☐ Following the third and subsequent courses of rituximab, the patient experienced at least a continuing 30% improvement in active joint count from baseline

and

☐ Rituximab re-treatment not to be given within 6 months of the previous course of treatment

and

☐ Maximum of two 1000 mg infusions given two weeks apart

Renewal — arthritis - rheumatoid - re-treatment for people who experience a response to rituximab

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

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

Prerequisites(tick boxes where appropriate)

- ☐ Following the initial course of rituximab infusions the patient experienced at least a 50% decrease in active joint count from baseline

or

- ☐ Following the second and subsequent courses of rituximab, the patient experienced at least a continuing 30% improvement in active joint count from baseline

and

☐ Rituximab re-treatment not to be given within 6 months of the previous course of treatment

and

☐ Maximum of two 1000 mg infusions per course given two weeks apart

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SA2157 - Adalimumab (Humira - Alternative brand)

Arthritis - polyarticular course juvenile idiopathic - Initial application 246
Arthritis - polyarticular course juvenile idiopathic - Renewal 246
Arthritis - psoriatic - Initial application 247
Arthritis - psoriatic - Renewal 247
Arthritis – oligoarticular course juvenile idiopathic - Initial application 246
Arthritis – oligoarticular course juvenile idiopathic - Renewal 246
Arthritis – rheumatoid - Initial application 247
Arthritis – rheumatoid - Renewal 248
Behcet's disease – severe - Initial application 238
Behcet's disease – severe - Renewal 238
Crohn's disease - adult - Initial application 241
Crohn's disease - adult - Renewal 241
Crohn's disease - children - Initial application 242
Crohn's disease - children - Renewal 242
Crohn's disease - fistulising - Initial application 242
Crohn's disease - fistulising - Renewal 243
Hidradenitis suppurativa - Initial application 238
Hidradenitis suppurativa - Renewal 239
Ocular inflammation – chronic - Initial application 243
Ocular inflammation – chronic - Renewal 244
Ocular inflammation – severe - Initial application 244
Ocular inflammation – severe - Renewal 245
Psoriasis - severe chronic plaque - Initial application 239
Psoriasis - severe chronic plaque - Renewal 240
Pyoderma gangrenosum - Initial application 240
Pyoderma gangrenosum - Renewal 241
Still's disease – adult-onset (AOSD) - Initial application 248
Still's disease – adult-onset (AOSD) - Renewal 248
Ankylosing spondylitis - Initial application 245
Ankylosing spondylitis - Renewal 245

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

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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

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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 Amgevitat

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

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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)

- ☐ The patient has had a good clinical response following 12 weeks' initial treatment

or

- ☐ Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema)

or

- ☐ Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old

and

- ☐ Adalimumab to be administered at doses no greater than 40 mg every 14 days

Initial application — Ocular inflammation – severe

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 – 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 7 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

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

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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)

☐ Patient has previously adequately responded* to 6 doses of omalizumab

or

☐ Patient has previously had a complete response* to 6 doses of omalizumab

and

☐ Patient has relapsed after cessation of omalizumab therapy

Note: *Inadequate response defined as less than 50% reduction in baseline UAS7 and DLQI score, or an increase in Urticaria Control Test (UCT) score of less than 4 from baseline. Patient is to be reassessed for response after 4 doses of omalizumab. Complete response is defined as UAS7 less than or equal to 6 and DLQI less than or equal to 5; or UCT of 16. Relapse of chronic urticaria on stopping prednisone/ciclosporin does not justify the funding of omalizumab.

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Siltuximab

Initial application
Applications only from 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

- ☐ 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)

- ☐ 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 — previously untreated chronic lymphocytic leukaemia in combination with venetoclax
Applications from any relevant practitioner. Approvals valid for 15 months.
Prerequisites(tick boxes where appropriate)

☐ Individual is currently on treatment with obinutuzumab and venetoclax and met all of the following criteria prior to commencing treatment

or

☐ Individual has previously untreated chronic lymphocytic leukaemia

and

☐ Obinutuzumab is to be administered at a maximum cumulative dose of 8,000 mg and in combination with venetoclax for a maximum of 6 (28-day) cycles of treatment

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 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 1.5×10^9/L and platelets greater than or equal to 75×10^9/L.

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Obinutuzumab *- continued*

Initial application — follicular / marginal zone lymphoma
Applications from any relevant practitioner. 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

Renewal — follicular / marginal zone lymphoma
Current approval Number (if known):.....
Applications from any relevant practitioner. Approvals valid for 24 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has no evidence of disease progression following obinutuzumab induction therapy
and
☐ Obinutuzumab to be administered at a maximum of 1000 mg every 2 months for a maximum of 2 years
and
☐ Obinutuzumab to be discontinued at disease progression

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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)

- ☐ Patient has locally advanced, non-metastatic, squamous cell cancer of the head and neck

and

- ☐ Cisplatin is contraindicated or has resulted in intolerable side effects

and

- ☐ Patient has an ECOG performance score of 0-2

and

- ☐ To be administered in combination with radiation therapy

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)

- ☐ Patient has metastatic colorectal cancer located on the left side of the colon (see Note)

and

- ☐ There is documentation confirming disease is RAS and BRAF wild-type

and

- ☐ Patient has an ECOG performance score of 0-2

and

- ☐ Patient has not received prior funded treatment with cetuximab

and

- ☐ Cetuximab is to be used in combination with chemotherapy

or

- ☐ Chemotherapy is determined to not be in the best interest of the patient based on clinician assessment

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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APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA2550
October 2026

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Aflibercept

Initial application — diabetic macular oedema
Applications from any relevant practitioner. 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

and

- ☐ Patient has not previously been treated with faricimab for longer than 3 months

Renewal — diabetic macular oedema

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

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

- ☐ There is stability or two lines of Snellen visual acuity gain

and

- ☐ There is structural improvement on OCT scan (with reduction in intra-retinal cysts, central retinal thickness, and sub-retinal fluid)

and

- ☐ Patient's vision is 6/36 or better on the Snellen visual acuity score

and

- ☐ There is no centre-involving sub-retinal fibrosis or foveal atrophy

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Aflibercept *- continued*

Initial application — wet age related macular degeneration
Applications from any relevant practitioner. 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 or faricimab for longer than 3 months

or

- ☐ Patient has current approval to use ranibizumab or faricimab for treatment of wAMD and was found to be intolerant within 3 months
  or
- ☐ Patient has previously* (*before June 2018) received treatment with ranibizumab for wAMD and disease was stable while on treatment

Renewal — wet age related macular degeneration

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

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

- ☐ Documented benefit must be demonstrated to continue

and

- ☐ Patient's vision is 6/36 or better on the Snellen visual acuity score

and

- ☐ There is no structural damage to the central fovea of the treated eye

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Secukinumab

Initial application — plaque psoriasis
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has "whole body" 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 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 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 DLQI score greater than 10

and

☐ Patient has received insufficient benefit (see Note) or has experienced intolerable side effects from at least 3 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 the most recent prior treatment course, within 1 month of stopping that treatment

and

☐ The most recent PASI or DQLI assessment is within 1 month before the application

or

☐ Patient has had a Special Authority approval for adalimumab, etanercept, or infliximab, for plaque psoriasis

and

☐ Patient has experienced intolerable side effects

or

☐ Patient has received insufficient benefit to meet the renewal criteria for plaque psoriasis

and

☐ A PASI assessment or DLQI assessment has been completed for the most recent prior treatment within 1 month of stopping that treatment

and

☐ The most recent PASI or DQLI assessment is within 1 month before the application

Note: A treatment course is defined as a minimum of 12 weeks of treatment. "Insufficient benefit" is defined as: for whole body plaque psoriasis, a PASI score of greater than 10; for 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 — plaque psoriasis

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 compared to pre-secukinumab baseline

or

☐ Patient has a DLQI improvement of 5 or more, compared to pre-secukinumab baseline

or

☐ Patient had localised genital or flexural plaque psoriasis at the start of treatment

and

☐ Patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, compared to the pre-secukinumab baseline

or

☐ Patient has a DLQI improvement of 5 or more, compared to pre-secukinumab baseline

and

☐ Maximum dose 300 mg monthly

Initial application — ankylosing spondylitis – second-line biologic

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

Prerequisites(tick boxes where appropriate)

☐ Patient has had a Special Authority approval for adalimumab or etanercept for ankylosing spondylitis

and

☐ Patient has experienced intolerable side effects

or

☐ Patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis

Renewal — ankylosing spondylitis – second-line biologic

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

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

Prerequisites(tick boxes where appropriate)

☐ BASDAI has improved from the pre-secukinumab baseline either by at least 4 points on a 10-point scale, or by at least 50%, whichever is less

and

☐ Maximum dose 300 mg monthly

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Secukinumab *- continued*

Initial application — arthritis - psoriatic

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

Prerequisites(tick boxes where appropriate)

☐ Patient has had a Special Authority approval for adalimumab, etanercept or infliximab for psoriatic arthritis

and

☐ Patient has experienced intolerable side effects

or

☐ Patient has received insufficient benefit to meet the renewal criteria for psoriatic arthritis

or

☐ Patient has received insufficient benefit from at least 3 months of methotrexate at a maximum tolerated dose unless contraindicated

and

☐ Patient has received insufficient benefit from at least 3 months of sulfasalazine or leflunomide at maximum tolerated doses unless contraindicated

and

☐ Patient has persistent symptoms of poorly controlled and active disease in at least 15 joints

or

☐ Patient has persistent symptoms of poorly controlled and active disease in at least 4 joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

☐ CRP greater than 15 mg/L measured within one month before the application

or

☐ ESR greater than 25 mm per hour measured within one month before the application

or

☐ ESR and CRP not measured as patient is receiving prednisone therapy greater than 5 mg per day received for more than 3 months

Renewal — arthritis - psoriatic

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

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

Prerequisites(tick boxes where appropriate)

☐ Following initial treatment, at least a 50% decrease in active joint count from baseline

or

☐ At least a continuing 30% improvement in active joint count from baseline

and

☐ Maximum dose 300 mg monthly

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SA2620 - Infliximab

Behcet disease - Initial application 272
Crohn's disease (adults) - Initial application 263
Crohn's disease (adults) - Renewal 263
Crohn's disease (children) - Initial application 264
Crohn's disease (children) - Renewal 264
Graft vs host disease - Initial application 264
Pulmonary sarcoidosis - Initial application 264
Acute fulminant ulcerative colitis - Initial application 265
Ankylosing spondylitis - Initial application 265
Ankylosing spondylitis - Renewal 265
Arthritis - psoriatic - Initial application 270
Arthritis - psoriatic - Renewal 271
Arthritis - rheumatoid - Initial application 271
Arthritis - rheumatoid - Renewal 271
Fistulising Crohn's disease - Initial application 267
Fistulising Crohn's disease - Renewal 267
Fulminant ulcerative colitis - Renewal 272
Immune checkpoint inhibitor toxicity in malignancy* - Initial application 276
Immune checkpoint inhibitor toxicity in malignancy* - Renewal 276
Inflammatory bowel arthritis – axial - Initial application 275
Inflammatory bowel arthritis – axial - Renewal 275
Inflammatory bowel arthritis – peripheral - Initial application 275
Inflammatory bowel arthritis – peripheral - Renewal 276
Neurosarcoidosis - Initial application 267
Neurosarcoidosis - Renewal 268
Ocular inflammation - chronic* - Initial application 266
Ocular inflammation - chronic* - Renewal 266
Ocular inflammation - severe* - Initial application 273
Ocular inflammation - severe* - Renewal 273
Plaque psoriasis - Initial application 268
Plaque psoriasis - Renewal 269
Previous use - Initial application 270
Pyoderma gangrenosum* - Initial application 274
Ulcerative colitis - Initial application 274
Ulcerative colitis - Renewal 274

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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

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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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)

- ☐ Patient has acute, fulminant ulcerative colitis

and

- ☐ Treatment with intravenous or high dose oral corticosteroids has not been successful

Initial application — ankylosing spondylitis
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has had a Special Authority approval for adalimumab or etanercept for ankylosing spondylitis

and

- ☐ Patient has experienced intolerable side effects

or

- ☐ Patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis

and

- ☐ Following initial induction doses, maximum dose 5mg/kg every 6-8 weeks

Renewal — ankylosing spondylitis

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

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

- ☐ BASDAI has improved from pre-treatment baseline either by at least 4 points on a 10-point scale, or by at least 50%

and

- ☐ Maximum dose 5 mg/kg every 6-8 weeks

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Infliximab *- continued*

Initial application — ocular inflammation - chronic*

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

Prerequisites(tick boxes where appropriate)

☐ Patient has had a Special Authority approval for adalimumab for chronic ocular inflammation

and

☐ Patient has experienced intolerable side effects

or

☐ Patient has received insufficient benefit to meet the renewal criteria for chronic ocular inflammation

or

☐ Patient has severe uveitis with a severe risk of vision loss uncontrolled by treatment with corticosteroids and other immunosuppressants

and

☐ Patient is 18 years or older and treatment with at least two other immunomodulatory agents has been ineffective or are contraindicated

or

☐ Patient is under 18 years and treatment with methotrexate has been ineffective, is contraindicated or is not tolerated at a therapeutic dose

or

☐ Patient is under 8 years and treatment with corticosteroids or methotrexate has been ineffective, is contraindicated 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

Note: Indications marked with * are unapproved indications

Renewal — ocular inflammation - chronic*

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

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

Prerequisites(tick boxes where appropriate)

☐ Patient has received a good clinical response following 3 initial doses

or

☐ Following each 2 year treatment period, the patient has experienced 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 corticosteroid sparing effect, allowing reduction in prednisone to < 10mg daily, or corticosteroid 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. Indications marked with * are unapproved indications

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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)

- ☐ 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

- ☐ Patent 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)

- ☐ The number of open draining fistulae have decreased from baseline by at least 50%

or

- ☐ There has been a marked reduction in drainage of all fistula(e) from baseline (in the case of adult patients, as demonstrated by a reduction in the Fistula Assessment score), together with less induration and patient reported pain

and

- ☐ Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. 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)

- ☐ Patient has been diagnosed with neurosarcoiosis by a multidisciplinary team

and

- ☐ Patient has CNS involvement

and

- ☐ Patient has steroid-refractory disease

and

- ☐ IV cyclophosphamide has been tried

or

- ☐ Treatment with IV cyclophosphamide is clinically inappropriate

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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)

- ☐ A withdrawal period has been tried and the patient has relapsed

or

- ☐ A withdrawal period has been considered but would not be clinically appropriate

and

- ☐ There has been a marked reduction in prednisone dose

and

- ☐ There has been an improvement in MRI appearances

or

- ☐ Marked improvement in other symptomology

Initial application — plaque psoriasis

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

Prerequisites(tick boxes where appropriate)

- ☐ Patient had a Special Authority approval for adalimumab, etanercept or secukinumab for plaque psoriasis

and

- ☐ Patient has experienced intolerable side effects

or

- ☐ Patient has received insufficient benefit to meet the renewal criteria for plaque psoriasis

or

- ☐ Patient has "whole body" plaque psoriasis with a PASI score of greater than 10

or

- ☐ Patient has plaque psoriasis of the face, or palm of a hand or sole of a foot

or

- ☐ Patient has localised genital or flexural plaque psoriasis with a DLQI score greater than 10

and

- ☐ Patient has received insufficient benefit (see Note) or has experienced intolerable side effects from at least 3 of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin

and

- ☐ A PASI assessment has been completed for the most recent prior treatment course within 1 month of stopping that treatment

and

- ☐ The most recent PASI assessment is within 1 month before the application

Note: "Insufficient benefit" is defined as: for whole body plaque psoriasis, a PASI score of greater than 10; for 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 2 years.

Prerequisites(tick boxes where appropriate)

- ☐ Patient had "whole body" plaque psoriasis at the start of treatment
  - **and**
- ☐ Patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-infliximab baseline

or

- ☐ Patient had plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment
  - **and**
- ☐ 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 pre-infliximab baseline
  - **or**
- ☐ Patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-infliximab baseline

or

- ☐ Patient had localised genital or flexural plaque psoriasis at the start of treatment
  - **and**
- ☐ 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
  - **or**
- ☐ Patient has a DLQI improvement of 5 or more, as compared to the pre-infliximab baseline

and

- ☐ Maximum dose 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 — arthritis - psoriatic
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has had a Special Authority approval for adalimumab or etanercept or secukinumab for psoriatic arthritis

and

☐ Patient has experienced intolerable side effects

or

☐ Patient has received insufficient benefit to meet the renewal criteria for psoriatic arthritis

and

☐ Following initial induction doses, maximum dose 5mg/kg every 8 weeks

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Infliximab *- continued*

Renewal — arthritis - psoriatic

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

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

Prerequisites(tick boxes where appropriate)

- ☐ Following initial treatment, at least a 50% decrease in active joint count from baseline
- **or**
- ☐ At least a continuing 30% improvement in active joint count from baseline

and

☐ Maximum dose 5 mg/kg every 8 weeks

Initial application — arthritis - rheumatoid

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

Prerequisites(tick boxes where appropriate)

☐ Patient has had a Special Authority approval for adalimumab or etanercept for rheumatoid arthritis

and

- ☐ Patient has experienced intolerable side effects
- **or**
- ☐ Patient has received insufficient benefit to meet the renewal criteria for rheumatoid arthritis

and

☐ Following initial induction doses, maximum dose 3mg/kg every 8 weeks

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 experienced at least a 50% decrease in active joint count from baseline
- **or**
- ☐ Patient has experienced at least a continuing 30% improvement in active joint count from baseline

and

☐ Maximum dose 3 mg/kg every 8 weeks

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Infliximab *- continued*

Initial application — Behcet disease

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

Prerequisites(tick boxes where appropriate)

☐ Patient has severe Behcet disease which is significantly impacting their quality of life

and

☐ Patient has severe ocular, neurological and/or vasculitic symptoms and has received insufficient benefit from 1 or more treatment(s) appropriate for the particular symptom(s)

or

☐ Patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has received insufficient benefit from 2 or more treatments appropriate for the particular symptom(s)

and

☐ Following initial loading doses, maximum dose 5mg/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)

☐ Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months

and

☐ Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. 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 — 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 adalimumab for severe ocular inflammation

and

☐ Patient has experienced intolerable side effects

or

☐ Patient has received insufficient benefit to meet the renewal criteria for severe ocular inflammation

or

☐ Patient has severe, vision-threatening ocular inflammation requiring rapid control

and

☐ Treatment with high-dose IV corticosteroids followed by high dose oral corticosteroids has been ineffective at controlling symptoms

or

☐ Patient developed new inflammatory symptoms while receiving high dose corticosteroids

or

☐ Patient is aged under 8 years and treatment with high dose oral corticosteroids and other immunosuppressants has been ineffective at controlling symptoms

or

☐ High dose corticosteroids are contraindicated

Note: Indications marked with * are unapproved indications.

Renewal — ocular inflammation - severe*

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

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

☐ Patient has received a good clinical response following 3 initial doses

or

☐ Following each 2 year treatment period, the patient has experienced 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, patient has a sustained corticosteroid sparing effect, allowing reduction in prednisone to < 10mg daily, or corticosteroid 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. Indications marked with * are unapproved indications

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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 from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has received insufficient benefit from 3 months of conventional therapy including a minimum of 3 pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate). Where conventional pharmaceuticals are contraindicated, a 3-month trial has occurred of those that are not contraindicated

and

- ☐ Maximum of 8 doses every 4 months

Note: Note: Indications marked with * are unapproved indications.

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Infliximab *- continued*

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

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

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Infliximab *- continued*

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

Initial application — immune checkpoint inhibitor toxicity in malignancy*

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

Prerequisites(tick boxes where appropriate)

- ☐ The individual requires treatment for moderate to severe autoimmune toxicity following immune checkpoint inhibitor treatment for malignancy

and

- ☐ The individual has received insufficient benefit from use of corticosteroids

and

- ☐ Infliximab is to be administered at up to 5mg/kg for up to four doses

Renewal — immune checkpoint inhibitor toxicity in malignancy*

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

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

Prerequisites(tick boxes where appropriate)

- ☐ The individual has shown clinical improvement and ongoing treatment is required

and

- ☐ Infliximab is to be administered at up to 5mg/kg for up to a total of 8 doses

Note: Indications marked with * are unapproved indications.

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SA2489 - Tocilizumab

Rheumatoid Arthritis - Initial application 280
Rheumatoid Arthritis - Renewal 282
Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept) - Initial application 279
Adult-onset Still's disease - Initial application 281
Adult-onset Still's disease - Renewal 283
Cytokine release syndrome - Initial application 278
Idiopathic multicentric Castleman's disease - Initial application 282
Idiopathic multicentric Castleman's disease - Renewal 283
Immune checkpoint inhibitor toxicity in malignancy* - Initial application 283
Immune checkpoint inhibitor toxicity in malignancy* - Renewal 284
Moderate to severe COVID-19 - Initial application 282
Polyarticular juvenile idiopathic arthritis - Initial application 281
Polyarticular juvenile idiopathic arthritis - Renewal 283
Previous use - Initial application 278
Systemic juvenile idiopathic arthritis - Initial application 280
Systemic juvenile idiopathic arthritis - Renewal 282

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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

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 — 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)

☐ Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer

and

☐ Tocilizumab is to be used as monotherapy

and

☐ Treatment with methotrexate is contraindicated

or

☐ Patient has tried and did not tolerate oral and/or parenteral methotrexate

and

☐ Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of ciclosporin alone or in combination with another agent

or

☐ Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of leflunomide alone or in combination with another agent

and

☐ Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints

or

☐ Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

☐ Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application

or

☐ C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

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)

☐ Patient diagnosed with systemic juvenile idiopathic arthritis

and

☐ Patient has tried and not responded to a reasonable trial of all of the following, either alone or in combination: oral or parenteral methotrexate; non-steroidal anti-inflammatory drugs (NSAIDs); and systemic corticosteroids

I confirm 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 — 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

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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 barcitinib

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)

☐ Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

☐ Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline

or

☐ On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

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

Initial application — immune checkpoint inhibitor toxicity in malignancy*

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

Prerequisites(tick boxes where appropriate)

☐ The individual requires treatment for moderate to severe autoimmune toxicity following immune checkpoint inhibitor treatment for malignancy

and

☐ The individual has received insufficient benefit from use of corticosteroids

and

☐ Tocilizumab is to be administered at a maximum dose of 8 mg/kg fortnightly

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Tocilizumab *- continued*

Renewal — immune checkpoint inhibitor toxicity in malignancy*

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

Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ The individual has shown clinical improvement and ongoing treatment is required

and

☐ Tocilizumab is to be administered at a maximum dose of 8 mg/kg fortnightly

Note: Indications marked with * are unapproved indications.

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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 axiliary lymph nodes following completion of surgery

and

- ☐ Patient has completed systemic neoadjuvant therapy with trastuzumab and chemotherapy prior to surgery

and

- ☐ Disease has not progressed during neoadjuvant therapy

and

- ☐ Patient has left ventricular ejection fraction of 45% or greater

and

- ☐ Adjuvant treatment with trastuzumab emtansine to be commenced within 12 weeks of surgery

and

- ☐ Trastuzumab emtansine to be discontinued at disease progression

and

- ☐ Total adjuvant treatment duration must not exceed 42 weeks (14 cycles)

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.

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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)

☐ The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine

and

☐ Treatment to be discontinued at disease progression

Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

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SA2689 - Rituximab

ABO-incompatible organ transplant - Initial application 288
ANCA associated vasculitis - Initial application 288
ANCA associated vasculitis - Renewal 288
Antibody-mediated organ transplant rejection - Initial application 288
B-cell acute lymphoblastic leukaemia/lymphoma* - Initial application 301
CD20+ low grade or follicular B-cell NHL - Initial application 300
CD20+ low grade or follicular B-cell NHL - Renewal 300
Chronic lymphocytic leukaemia - Initial application 289
Chronic lymphocytic leukaemia - Renewal 290
Membranous nephropathy - Initial application 301
Post-transplant - Initial application 291
Post-transplant - Renewal 291
Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS) - Initial application 292
Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS) - Renewal 292
Steroid resistant nephrotic syndrome (SRNS) - Initial application 293
Steroid resistant nephrotic syndrome (SRNS) - Renewal 293
Aggressive CD20 positive NHL - Initial application 293
Aggressive CD20 positive NHL - Renewal 294
Anti-NMDA receptor autoimmune encephalitis* - Initial application 300
Antisynthetase syndrome - Initial application 299
Chronic inflammatory demyelinating polyneuropathy (CIPD)* - Initial application 299
Desensisation prior to transplant - Initial application 301
Graft versus host disease - Initial application 299
Haemophilia with inhibitors - Initial application 294
Haemophilia with inhibitors - Renewal 294
Immune thrombocytopenic purpura (ITP) - Initial application 295
Immune thrombocytopenic purpura (ITP) - Renewal 295
Immunoglobulin G4-related disease (IgG4-RD*) - Initial application 303
Immunoglobulin G4-related disease (IgG4-RD*) - Renewal 303
Indolent, low-grade lymphomas or hairy cell leukaemia* - Initial application 296
Indolent, low-grade lymphomas or hairy cell leukaemia* - Renewal 296
Neuromyelitis optica spectrum disorder (NMOSD)* - Initial application 290
Pemiphigus* - Initial application 302
Pemiphigus* - Renewal 302
Pure red cell aplasia (PRCA) - Initial application 296
Pure red cell aplasia (PRCA) - Renewal 296
Refractory myasthenia gravis* - Initial application 291
Refractory myasthenia gravis* - Renewal 292
Severe cold haemagglutinin disease (CHAD) - Initial application 297
Severe cold haemagglutinin disease (CHAD) - Renewal 297
Thrombotic thrombocytopenic purpura (TTP)* - Initial application 297
Treatment refractory systemic lupus erythematosus (SLE)* - Initial application 298
Warm autoimmune haemolytic anaemia (warm AIHA) - Initial application 298
Warm autoimmune haemolytic anaemia (warm AIHA) - Renewal 298

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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^2 of body-surface area per week for a total of 4 weeks

and

☐ Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months

or

☐ Patient has previously had a cumulative dose of cyclophosphamide > 15 g or a further repeat 3 month induction course of cyclophosphamide would result in a cumulative dose > 15 g

or

☐ Cyclophosphamide and methotrexate are contraindicated

or

☐ Patient is a female of child-bearing potential

or

☐ Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy

Note: Indications marked with * are unapproved indications.

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^2 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 and rituximab treatment is to be used in combination with funded venetoclax

and

☐ The patient has good performance status

and

☐ Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles

and

☐ It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), bendamustine or venetoclax

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to < 2.

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

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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 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

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

Prerequisites(tick boxes where appropriate)

- ☐ Cumulative dose up to 1,500 mg/m^2 body surface area up to 2,000 mg total per cycle

and

- ☐ Patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms with supporting clinical investigations)

or

- ☐ Patient has experienced a breakthrough attack of NMOSD

and

- ☐ Patient is receiving treatment with mycophenolate unless contraindicated or not tolerated

and

- ☐ Patient is receiving treatment with corticosteroids unless contraindicated or not tolerated

and

- ☐ Each treatment cycle at least 6 months apart

Note: Indications marked with * are unapproved indications.

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Rituximab (Riximyo) - *continued*

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.

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

- ☐ Cumulative dose up to 1,500 mg/m^2 body surface area up to 2,000 mg total per cycle
- **and**
  - ☐ Treatment with corticosteroids and at least one other immunosuppressant for a minimum 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

Note: Indications marked with * are unapproved indications.

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Rituximab (Riximyo) - *continued*

Renewal — refractory myasthenia gravis*

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

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

Prerequisites(tick boxes where appropriate)

- ☐ Cumulative dose up to 1,500 mg/m^2 body surface area up to 2,000 mg total per cycle

and

- ☐ An initial response lasting at least 12 months was demonstrated

and

- ☐ Patient has relapsed despite treatment with corticosteroids and at least one other immunosuppressant for a period of at least 12 months

or

- ☐ 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

Note: Indications marked with * are unapproved indications.

Initial application — Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)

Applications from any relevant practitioner. Approvals valid for 8 weeks.

Prerequisites(tick boxes where appropriate)

- ☐ Patient is a child with SDNS* or FRNS*

and

- ☐ Treatment with corticosteroids, ciclosporin, and mycophenolate for at least 3 months for each agent has been ineffective, not tolerated, or is contraindicated

and

- ☐ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

Renewal — Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)

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

Applications from any relevant practitioner. 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^2 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*

Initial application — Steroid resistant nephrotic syndrome (SRNS)
Applications from any relevant practitioner. Approvals valid for 8 weeks.
Prerequisites(tick boxes where appropriate)

- ☐ Patient is a child with SRNS* and treatment with corticosteroids, ciclosporin and tacrolimus for at least 3 months for each agent has been ineffective, not tolerated, or is contraindicated

and

- ☐ Genetic causes of nephrotic syndrome have been excluded

and

- ☐ The total rituximab dose per cycle would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

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)

- ☐ Patient who was previously treated with rituximab for nephrotic syndrome*

and

- ☐ Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment

and

- ☐ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

Initial application — aggressive CD20 positive NHL
Applications from any relevant practitioner. Approvals valid for 12 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has treatment naive aggressive CD20 positive NHL

and

- ☐ To be used with a multi-agent chemotherapy regimen given with curative intent

and

- ☐ To be used for a maximum of 8 treatment cycles

or

- ☐ The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy

and

- ☐ To be used for a maximum of 6 treatment cycles

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

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Rituximab (Riximyo) - *continued*

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)

- ☐ The patient has had a rituximab treatment-free interval of 12 months or more

and

- ☐ The patient has relapsed refractory/aggressive CD20 positive NHL

and

- ☐ To be used with a multi-agent chemotherapy regimen given with curative intent

and

- ☐ To be used for a maximum of 4 treatment cycles

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

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)

- ☐ Patient has mild congenital haemophilia complicated by inhibitors

or

- ☐ Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy

or

- ☐ Patient has acquired haemophilia

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)

- ☐ Patient was previously treated with rituximab for haemophilia with inhibitors

and

- ☐ An initial response lasting at least 12 months was demonstrated

and

- ☐ Patient now requires repeat treatment

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Rituximab (Riximyo) - *continued*

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)

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

or

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

and

☐ Treatment with steroids and splenectomy have been ineffective

or

☐ Treatment with steroids has been ineffective and splenectomy is an absolute contraindication

or

☐ Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy)

and

☐ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Note: Indications marked with * are unapproved indications.

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)

☐ Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned

or

☐ Patient was previously treated with rituximab for immune thrombocytopenic purpura*

and

☐ An initial response lasting at least 12 months was demonstrated

and

☐ Patient now requires repeat treatment

Note: Indications marked with * are unapproved indications.

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Rituximab (Riximyo) - *continued*

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)

☐ The patient has indolent low grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy
and
☐ To be used for a maximum of 6 treatment cycles

or

☐ The patient has indolent, low grade lymphoma or hairy cell leukaemia* requiring first-line systemic chemotherapy
and
☐ To be used for a maximum of 6 treatment cycles

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

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)

☐ The patient has had a rituximab treatment-free interval of 12 months or more
and
☐ The patient has indolent, low-grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy
and
☐ To be used for no more than 6 treatment cycles

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. *Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

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.

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Rituximab (Riximyo) - *continued*

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^2 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^2 weekly for 4 weeks) is now planned

or

- ☐ Patient was previously treated with rituximab for severe cold haemagglutinin disease*

and

- ☐ An initial response lasting at least 12 months was demonstrated

and

- ☐ Patient now requires repeat treatment

Note: Indications marked with * are unapproved indications.

Initial application — thrombotic thrombocytopenic purpura (TTP)*
Applications only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ The total rituximab dose per cycle would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

and

- ☐ Each treatment cycle at least 6 months apart

and

- ☐ Patient has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange

or

- ☐ Patient has acute idiopathic TTP* with neurological or cardiovascular pathology

or

- ☐ Patient has a history of immune-mediated thrombotic thrombocytopenic purpura, currently in clinical remission but has demonstrated a decline in ADAMTS13 levels or equivalent, consistent with high risk of relapse

Note: Indications marked with * are unapproved indications.

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Rituximab (Riximyo) - *continued*

Initial application — treatment refractory systemic lupus erythematosus (SLE)*
Applications only from a rheumatologist, nephrologist or any relevant practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid without further renewal unless notified.

Prerequisites(tick boxes where appropriate)

- ☐ Patient has severe, immediately life- or organ-threatening SLE*

and

- ☐ The condition has been refractory to treatment with corticosteroids at a dose of at least 1 mg/kg unless contraindicated

and

- ☐ The condition 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

- ☐ Initial treatment maximum of four 1000 mg infusions

and

- ☐ Treatment for relapse following initial partial response to rituximab up to a maximum of two 1000 mg infusions every 6 months

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^2 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^2 weekly for 4 weeks) is now planned

or

- ☐ Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia*

and

- ☐ An initial response lasting at least 12 months was demonstrated

and

- ☐ Patient now requires repeat treatment

Note: Indications marked with * are unapproved indications.

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Rituximab (Riximyo) - *continued*

Initial application — antisynthetase syndrome
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has severe, immediately life- or organ-threatening disease, including interstitial lung disease

and

- ☐ Treatment with at least 3 immunosuppressants (oral corticosteroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has been ineffective controlling active disease

or

- ☐ Rapid treatment is required for life threatening complications

and

- ☐ Maximum of two 1000mg infusions every 6 months

Initial application — graft versus host disease
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has refractory graft versus host disease following transplant

and

- ☐ Treatment with at least 3 immunosuppressants (oral steroids, ciclosporin, tacrolimus, mycophenolate, sirolimus) has not be effective at controlling active disease

and

- ☐ The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

Initial application — chronic inflammatory demyelinating polyneuropathy (CIPD)*
Applications only from a neurologist or any relevant practitioner on the recommendation of a neurologist. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ Treatment with corticosteroids and intravenous immunoglobulin and/or plasma exchange has been ineffective controlling active disease, is not tolerated, or is contraindicated

and

- ☐ At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) is not tolerated or has been ineffective controlling active disease. If an immunosuppressant is contraindicated, a trial has occurred of one of those which is not contraindicated (unless all are contraindicated)

or

- ☐ Rapid treatment is required for life threatening complications

and

- ☐ Cumulative dose up to 1500 mg/m^2 body surface area up to 2000 mg total per cycle

and

- ☐ Each treatment cycle at least 6 months apart

Note: Indications marked with * are unapproved indications.

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Rituximab (Riximyo) - *continued*

Initial application — anti-NMDA receptor autoimmune encephalitis*
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ Treatment with corticosteroids and intravenous immunoglobulin and/or plasma exchange has been ineffective controlling active disease, is not tolerated or is contraindicated
- **and**
- ☐ At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has been ineffective controlling active disease, is not tolerated or is contraindicated

or

- ☐ Rapid treatment is required for life threatening complications

and

- ☐ Cumulative dose up to 1500 mg/m^2 body surface area up to 2000 mg total per cycle

and

- ☐ Each treatment cycle at least 6 months apart

Note: Indications marked with * are unapproved indications.

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

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)

- ☐ Rituximab is to be used for maintenance in CD20+ low grade or follicular B-cell NHL following induction with first-line systemic chemotherapy
- **and**
- ☐ Patient is intended to receive rituximab maintenance therapy for 2 years at a dose of 375 mg/m^2 every 8 weeks (maximum of 12 cycles)

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Rituximab (Riximyo) - *continued*

Initial application — Membranous nephropathy
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Patient has biopsy-proven primary/idiopathic membranous nephropathy*

or

☐ Patient has PLA2 antibodies with no evidence of secondary cause, and an eGFR of > 60ml/min/1.73m^2

and

☐ Patient remains at high risk of progression to end-stage kidney disease despite more than 3 months of treatment with conservative measures that include (unless contraindicated or the patient has experienced intolerable side effects) renin-angiotensin system blockade, blood-pressure management, dietary sodium and protein restriction, treatment of dyslipidaemia, and anticoagulation agents

and

☐ The total rituximab dose per cycle would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks

and

☐ Subsequent retreatment only for disease relapse or after partial response

Note: Indications marked with * are unapproved indications.

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^2 per dose for a maximum of 18 doses

Note: Indications marked with * are unapproved indications.

Initial application — desensisation 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^2 of body-surface area

Note: Indications marked with * are unapproved indications.

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Rituximab (Riximyo) - *continued*

Initial application — pemiphigus*

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 — pemiphigus*

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)

☐ Patient has confirmed diagnosis of IgG4-RD*

and

☐ Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs for at least 3 months has been ineffective in lowering corticosteroid dose below 5 mg per day (prednisone equivalent) without relapse

or

☐ Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs is contraindicated or associated with evidence of toxicity or intolerance

and

☐ Total rituximab dose used should not exceed a maximum of two 1000 mg infusions of rituximab given two weeks apart

Note: Indications marked with * are unapproved indications.

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)

☐ Treatment with rituximab for IgG4-RD* was previously successful and patient's disease has demonstrated sustained response, but the condition has relapsed

or

☐ Patient is receiving maintenance treatment for IgG4-RD*

and

☐ Rituximab re-treatment not to be given within 6 months of previous course of treatment

and

☐ Maximum of two 1000 mg infusions of rituximab given two weeks apart

Note: Indications marked with * are unapproved indications.

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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 × 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

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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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)

☐ The patient has eosinophilic granulomatosis with polyangiitis

and

☐ The patient has trialled and not received adequate benefit from at least one of the following for at least three months (unless contraindicated to all): azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate, or rituximab

and

☐ The patient has trialled prednisone for a minimum of three months and is unable to maintain disease control at doses below 7.5 mg per day

or

☐ Corticosteroids are contraindicated

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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SA2525 - Adalimumab (Amgevita)

Arthritis - oligoarticular course juvenile idiopathic - Initial application 314
Arthritis - oligoarticular course juvenile idiopathic - Renewal 314
Arthritis - polyarticular course juvenile idiopathic - Initial application 315
Arthritis - polyarticular course juvenile idiopathic - Renewal 315
Arthritis - psoriatic - Initial application 316
Arthritis - psoriatic - Renewal 316
Arthritis - rheumatoid - Initial application 317
Arthritis - rheumatoid - Renewal 317
Behcet's disease - severe - Initial application 307
Crohn's disease - adults - Initial application 310
Crohn's disease - adults - Renewal 310
Crohn's disease - children - Initial application 310
Crohn's disease - children - Renewal 311
Crohn's disease - fistulising - Initial application 311
Crohn's disease - fistulising - Renewal 311
Hidradenitis suppurativa - Initial application 307
Hidradenitis suppurativa - Renewal 307
Ocular inflammation - chronic - Initial application 312
Ocular inflammation - chronic - Renewal 312
Ocular inflammation - severe - Initial application 312
Ocular inflammation - severe - Renewal 313
Plaque psoriasis - severe chronic - Initial application 308
Plaque psoriasis - severe chronic - Renewal 309
Still's disease - adult-onset (AOSD) - Initial application 318
Ankylosing spondylitis - Initial application 313
Ankylosing spondylitis - Renewal 314
Inflammatory bowel arthritis – axial - Initial application 319
Inflammatory bowel arthritis – axial - Renewal 320
Inflammatory bowel arthritis – peripheral - Initial application 320
Inflammatory bowel arthritis – peripheral - Renewal 320
Pyoderma gangrenosum - Initial application 309
Ulcerative colitis - Initial application 318
Ulcerative colitis - Renewal 318
Undifferentiated spondyloarthritis - Initial application 319
Undifferentiated spondyloarthritis - Renewal 319

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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)

☐ The patient has severe Behcet's disease* that is significantly impacting the patient's quality of life

and

☐ The patient has severe ocular, neurological, and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s)

or

☐ The patient has severe gastrointestinal, rheumatological, and/or mucocutaneous symptoms and has not responded adequately to two or more treatments appropriate for the particular symptom(s)

Note: Indications marked with * are unapproved indications.

Initial application — Hidradenitis suppurativa
Applications only from a dermatologist. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas

and

☐ Patient has tried, but had an inadequate response to at least a 90 day trial of systemic antibiotics or has demonstrated intolerance to or has contraindications for systemic antibiotics

and

☐ Patient has 3 or more active lesions

and

☐ The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application

Renewal — Hidradenitis suppurativa

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

Applications from any relevant practitioner. Approvals valid for 2 years.
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 DLQI improvement of 4 or more 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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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

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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

or

☐ 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

or

☐ 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)

or

☐ Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline

or

☐ On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

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

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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)

- ☐ Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis

and

  - ☐ The patient has experienced intolerable side effects

  or

  - ☐ The patient has received insufficient benefit from to meet the renewal criteria for psoriatic arthritis

or

- ☐ Patient has had active psoriatic arthritis for six months duration or longer

and

- ☐ Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated)

and

- ☐ Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated)

and

  - ☐ 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

and

  - ☐ Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application

  or

  - ☐ Patient has an ESR greater than 25 mm per hour

  or

  - ☐ ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

Renewal — Arthritis - psoriatic

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 swollen joint count from baseline and a clinically significant response in the opinion of the physician

or

- ☐ 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 (unless contraindicated)

or

- ☐ Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide (unless contraindicated) 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

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

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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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

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Palivizumab

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

☐ Palivizumab to be administered during the annual RSV season

and

☐ Infant was born in the last 12 months

and

☐ Infant was born at less than 32 weeks zero days' gestation

and

☐ Infant is to be administered palivizumab within a single calendar year

or

☐ Child was born in the last 24 months

and

☐ Child has severe lung, airway, neurological or neuromuscular disease that requires ongoing ventilatory/respiratory support (see Note A) in the community

or

☐ Child has haemodynamically significant heart disease

and

☐ Child has unoperated simple congenital heart disease with significant left to right shunt (see Note B)

or

☐ Child has unoperated or surgically palliated complex congenital heart disease

or

☐ Child has severe pulmonary hypertension (see Note C)

or

☐ Child has moderate or severe left ventricular (LV) failure (see Note D)

or

☐ Child has severe combined immune deficiency, confirmed by an immunologist, but has not received a stem cell transplant

or

☐ Child has inborn errors of immunity (see Note E) that increase susceptibility to life-threatening viral respiratory infections, confirmed by an immunologist

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

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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^2 body surface area or up to 2 vials of 5 mg as separate doses)

Note: Acute myeloid leukaemia excludes acute promyelocytic leukaemia and acute myeloid leukaemia that is secondary to another haematological disorder (eg myelodysplasia or myeloproliferative disorder).

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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 × 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)

- ☐ Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment

or

- ☐ Patient has active Crohn's disease

and

- ☐ Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

- ☐ Patient meets the initiation criteria for prior biologic therapies for Crohn's disease

and

- ☐ Other biologics for Crohn's disease are contraindicated

Note: Indication marked with * is an unapproved indication.

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)

- ☐ PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy

or

- ☐ PCDAI score is 15 or less

or

- ☐ The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed

and

- ☐ Ustekinumab to administered at a dose no greater than 90 mg every 8 weeks

Note: Indication marked with * is an unapproved indication.

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 — ulcerative colitis
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 ulcerative colitis

and

- ☐ Patient has had an initial approval for prior biologic therapy for ulcerative colitis and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

- ☐ Patient meets the initiation criteria for prior biologic therapies for ulcerative colitis

and

- ☐ Other biologics for ulcerative colitis are contraindicated

Renewal — ulcerative colitis

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

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

- ☐ The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy

or

- ☐ PUCAI score has reduced by 10 points or more from the PUCAI score since initiation on biologic therapy*

and

- ☐ Ustekinumab will be used at a dose no greater than 90 mg intravenously every 8 weeks

Note: Criterion marked with * is for an unapproved indication.

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

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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

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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 — CD30 positive systemic anaplastic large-cell lymphoma
Applications from any relevant practitioner. Approvals valid for 12 months.
Prerequisites(tick boxes where appropriate)

☐ Patient is currently on treatment with brentuximab vedotin and met all the following criteria prior to commencing treatment

or

☐ Patient has CD30 positive systemic anaplastic large-cell lymphoma

and

☐ Patient must have histological confirmation of CD30 expression

and

☐ Patient must not have received prior treatment with curative intent chemotherapy for this condition

and

☐ Treatment must be in combination with cyclophosphamide, anthracycline, and steroids for a maximum of 8 cycles

and

☐ Brentuximab vedotin is to be administered at doses no greater than 1.8 mg/kg every 3 weeks

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

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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Brentuximab *- continued*

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 — relapsed/refractory anaplastic large cell lymphoma

Applications from any relevant practitioner. Approvals valid for 9 months.

Prerequisites(tick boxes where appropriate)

- ☐ Patient has relapsed/refractory CD30-positive systemic anaplastic large cell lymphoma

and

- ☐ Patient has an ECOG performance status of 0-1

and

- ☐ Patient has not previously received brentuximab vedotin

and

- ☐ Response to brentuximab vedotin treatment is to be reviewed after a maximum of 6 treatment cycles

and

- ☐ Brentuximab vedotin to be administered at doses no greater than 1.8 mg/kg every 3 weeks

Renewal — relapsed/refractory 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 experienced 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

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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)

☐ The patient has locally advanced or metastatic gastric, gastro-oesophageal junction or oesophageal cancer expressing HER-2 IHC 2+ FISH+ or IHC3+ (or other current technology)

and

☐ Patient has an ECOG score of 0-2

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)

☐ 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

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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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Bevacizumab

Initial application — unresectable hepatocellular carcinoma
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Patient is currently on treatment with bevacizumab, and met all remaining criteria prior to commencing treatment

or

☐ Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma

and

☐ Patient has preserved liver function (Child-Pugh A)

and

☐ Transarterial chemoembolisation (TACE) is unsuitable

and

☐ Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma

or

☐ Patient received funded lenvatinib before 1 March 2025

or

☐ Patient has experienced treatment-limiting toxicity from treatment with lenvatinib

and

☐ No disease progression since initiation of lenvatinib

and

☐ Patient has an ECOG performance status of 0-2

and

☐ To be given in combination with atezolizumab

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

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Bevacizumab *- continued*

Initial application — advanced or metastatic ovarian cancer
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ The patient has FIGO Stage IV epithelial ovarian, fallopian tube, or primary peritoneal cancer

or

☐ The patient has previously untreated advanced (FIGO Stage IIIB or IIIC) epithelial ovarian, fallopian tube, or primary peritoneal cancer

and

☐ Debulking surgery is inappropriate

or

☐ The cancer is sub-optimally debulked (maximum diameter of any gross residual disease greater than 1cm)

and

☐ Bevacizumab to be administered at a maximum dose of 15 mg/kg every three weeks

and

☐ 18 weeks concurrent treatment with chemotherapy is planned

Renewal — advanced or metastatic ovarian cancer

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

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

☐ Maximum of 6 doses

and

☐ The patient has recurrent respiratory papillomatosis

and

☐ The treatment is for intra-lesional administration

Renewal — Recurrent Respiratory Papillomatosis

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

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

☐ Maximum of 6 doses

and

☐ The treatment is for intra-lesional administration

and

☐ There has been a reduction in surgical treatments or disease regrowth as a result of treatment

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Bevacizumab *- continued*

Initial application — Ocular Conditions
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Ocular neovascularisation

or

☐ Exudative ocular angiopathy

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Inotuzumab ozogamicin

Initial application
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 relapsed or refractory CD22-positive B-cell acute lymphoblastic leukaemia/lymphoma, including minimal residual disease
- **and** ☐ Patient has ECOG performance status of 0-2
- **and**
  - ☐ Patient has Philadelphia chromosome positive B-Cell ALL
  - **and** ☐ Patient has previously received a tyrosine kinase inhibitor
  - **or** ☐ Patient has received one prior line of treatment involving intensive chemotherapy
- **and** ☐ Treatment is to be administered for a maximum of 3 cycles

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 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient is not proceeding to a stem cell transplant
- **and**
  - ☐ Patient has experienced complete disease response
  - **or** ☐ Patient has experienced complete remission with incomplete haematological recovery
- **and** ☐ Treatment with inotuzumab ozogamicin is to cease after a total duration of 6 cycles

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Faricimab

Initial application — diabetic macular oedema
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has centre involving diabetic macular oedema (DMO)

and

- ☐ Patient's disease is nonresponsive 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

and

- ☐ Patient has not previously been treated with aflibercept for longer than 3 months

Renewal — diabetic macular oedema

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

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

- ☐ There is stability or two lines of Snellen visual acuity gain

and

- ☐ There is structural improvement on OCT scan (with reduction in intra-retinal cysts, central retinal thickness, and sub-retinal fluid)

and

- ☐ Patient's vision is 6/36 or better on the Snellen visual acuity score

and

- ☐ There is no centre-involving sub-retinal fibrosis or foveal atrophy

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Faricimab *- continued*

Initial application — wet age related macular degeneration
Applications from any relevant practitioner. 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 or aflibercept for longer than 3 months

Renewal — wet age related macular degeneration

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

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

- ☐ Patient's vision is 6/36 or better on the Snellen visual acuity score

and

- ☐ There is no structural damage to the central fovea of the treated eye

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Pertuzumab with trastuzumab

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

☐ The individual has received an initial Special Authority approval for intravenous pertuzumab and trastuzumab for metastatic breast cancer

and

☐ Pertuzumab with trastuzumab to be administered subcutaneously at a maximum dose of 600 mg pertuzumab with 600 mg trastuzumab every three weeks (or equivalent)

or

☐ 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

☐ Loading dose of pertuzumab with trastuzumab to be administered subcutaneously at a maximum dose of 1200 mg pertuzumab with 600 mg trastuzumab, respectively

and

☐ Maintenance doses of pertuzumab with trastuzumab to be administered subcutaneously at a maximum dose of 600 mg pertuzumab with 600 mg trastuzumab every three weeks (or equivalent)

and

☐ Pertuzumab with 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 individual 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

☐ Individual has previously discontinued treatment with pertuzumab with trastuzumab for reasons other than severe toxicity or disease progression

and

☐ Individual has signs of disease progression

and

☐ Disease has not progressed during previous treatment with pertuzumab with trastuzumab

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Nivolumab

Initial application — stage III or IV resectable melanoma
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 individual is currently on treatment with nivolumab for neoadjuvant treatment of resectable stage IIIB, IIIC, IIID or IV melanoma and met all remaining criteria prior to commencing treatment

or

☐ The individual has resectable stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note)

and

☐ The individual has not received prior funded systemic treatment in the perioperative setting for their stage IIIB, IIIC, IIID or IV melanoma

and

☐ The individual has ECOG performance score 0-2

and

☐ Treatment must be initiated prior to complete surgical resection

and

☐ Neoadjuvant nivolumab must be administered in combination with ipilimumab

and

☐ Nivolumab to be administered for maximum of two cycles prior to surgical resection

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

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Nivolumab *- continued*

Renewal — stage III or IV resectable melanoma

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 individual has received funded neoadjuvant treatment with nivolumab in combination with ipilimumab
- **and** ☐ Adjuvant treatment with nivolumab is required
- **and** ☐ Treatment must be initiated within 13 weeks of complete surgical resection, unless delay is necessary due to post-surgery recovery
- **and** ☐ Nivolumab must be administered as monotherapy
- **and** ☐ Nivolumab to be discontinued at signs of disease recurrence or at completion of 12 months total treatment duration including any systemic neoadjuvant treatment (equivalent to 11 adjuvant cycles at 480 mg every 4 weeks plus initial 2 neoadjuvant treatment cycles)

or

- ☐ The individual has received neoadjuvant treatment with nivolumab and ipilimumab
- **and** ☐ The individual has unresectable or metastatic melanoma (excluding uveal) stage III or IV
- **and** ☐ The individual meets initial application criteria for nivolumab for unresectable or metastatic melanoma

or

- ☐ The individual has received neoadjuvant treatment with nivolumab and ipilimumab
- **and** ☐ The individual has received treatment with nivolumab for unresectable or metastatic melanoma
- **and** ☐ The individual meets the renewal criteria for nivolumab for unresectable or metastatic melanoma

Note:

a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition.

b) Disease must be completely resectable and amenable to curative intent surgery, including stage IV disease.

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Nivolumab *- continued*

Initial application — unresectable or metastatic melanoma
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 individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV

and

- ☐ Baseline measurement of overall tumour burden is documented clinically and radiologically

and

- ☐ The individual has ECOG performance 0-2

and

- ☐ The individual has not received funded pembrolizumab

or

- ☐ The individual has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance

and

- ☐ The cancer did not progress while the indvidual was on pembrolizumab

and

- ☐ The individual has been diagnosed in the metastatic or unresectable stage III or IV setting

or

- ☐ The individual did not receive treatment in the perioperative setting with a PD-1/PD-L1 inhibitor

or

- ☐ The individual received treatment in the perioperative setting with a PD-1/PD-L1 inhibitor

and

- ☐ The individual did not experience disease recurrence while on treatment with that PD-1/PD-L1 inhibitor

and

- ☐ The individual did not experience disease recurrence within six months of completing perioperative treatment with a PD-1/PD-L1 inhibitor

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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Nivolumab *- continued*

Renewal — unresectable or metastatic melanoma, less than 24 months on treatment

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 individual's disease has had a complete response to treatment
  - **or**
- ☐ The individual's disease has had a partial response to treatment
  - **or**
- ☐ The individual has stable disease

and

- ☐ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

or

- ☐ The individual has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression

and

- ☐ The individual has signs of disease progression

and

- ☐ Disease has not progressed during previous treatment with nivolumab

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

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Nivolumab *- continued*

Renewal — unresectable or metastatic melanoma, more than 24 months on treatment

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 individual has been on treatment for more than 24 months

and

☐ The individual's disease has had a complete response to treatment

or

☐ The individual's disease has had a partial response to treatment

or

☐ The individual has stable disease

and

☐ Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period

or

☐ The individual has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression

and

☐ The individual has signs of disease progression

and

☐ Disease has not progressed during previous treatment with nivolumab

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

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Nivolumab *- continued*

Initial application — renal cell carcinoma, first line
Applications from any relevant practitioner. 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

☐ The patient has metastatic renal cell carcinoma

and

☐ The patient is treatment naive

and

☐ The patient has ECOG performance status 0-2

and

☐ The disease is predominantly of clear cell histology

and

☐ The patient has sarcomatoid histology

or

☐ Haemoglobin levels less than the lower limit of normal

or

☐ Corrected serum calcium level greater than 10 mg/dL (2.5 mmol/L)

or

☐ Neutrophils greater than the upper limit of normal

or

☐ Platelets greater than the upper limit of normal

or

☐ Interval of less than 1 year from original diagnosis to the start of systemic therapy

or

☐ Karnofsky performance score of less than or equal to 70

and

☐ Nivolumab is to be used in combination with ipilimumab for the first four treatment cycles at a maximum dose of 3 mg/kg

and

☐ Nivolumab is to be used as monotherapy at a maximum maintenance dose of 240 mg every 2 weeks (or equivalent)

Initial application — Renal cell carcinoma, second line
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has metastatic renal-cell carcinoma

and

☐ The disease is of predominant clear-cell histology

and

☐ Patient has ECOG performance status 0-2

and

☐ Patient has documented disease progression following one or two previous regimens of antiangiogenic therapy

and

☐ Patient has not previously received a funded immune checkpoint inhibitor

and

☐ Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression

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

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Nivolumab *- continued*

Renewal — Renal cell carcinoma

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

Applications from any relevant practitioner. 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

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SA2631 - Pembrolizumab

MSI-H/dMMR advanced colorectal cancer - Initial application 364
MSI-H/dMMR advanced colorectal cancer - Renewal 365
Urothelial carcinoma - Initial application 365
Urothelial carcinoma - Renewal 365
Breast cancer, advanced - Initial application 362
Breast cancer, advanced - Renewal 363
Head and neck squamous cell carcinoma - Initial application 363
Head and neck squamous cell carcinoma - Renewal 364
Non-small cell lung cancer first line combination therapy - Renewal 361
Non-small cell lung cancer first line monotherapy - Renewal 360
Non-small cell lung cancer first-line combination therapy - Initial application 360
Non-small cell lung cancer first-line monotherapy - Initial application 359
Relapsed/refractory Hodgkin lymphoma - Initial application 366
Relapsed/refractory Hodgkin lymphoma - Renewal 366
Stage III or IV resectable melanoma - neoadjuvant - Initial application 352
Stage III or IV resectable melanoma - neoadjuvant - Renewal 353
Stage III or IV resected melanoma - adjuvant - Initial application 354
Stage III or IV resected melanoma - adjuvant - Renewal 355
Unresectable or metastatic melanoma - Initial application 356
Unresectable or metastatic melanoma, less than 24 months on treatment - Renewal 357
Unresectable or metastatic melanoma, more than 24 months on treatment - Renewal 358

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Pembrolizumab

Initial application — stage III or IV resectable melanoma - neoadjuvant
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 individual has resectable stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note)

and

- ☐ The individual has not received prior funded systemic treatment in the perioperative setting for their stage IIIB, IIIC, IIID or IV melanoma

and

- ☐ Treatment must be prior to complete surgical resection

and

- ☐ Pembrolizumab must be administered as monotherapy

and

- ☐ The individual has ECOG performance score 0-2

and

- ☐ Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent)

I confirm 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 — stage III or IV resectable melanoma - neoadjuvant

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 individual has received neoadjuvant treatment with an immune checkpoint inhibitor
  and
- ☐ The individual meets initial application criteria for pembrolizumab for stage III or IV resected melanoma – adjuvant

or

- ☐ The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor
  and
- ☐ The individual meets renewal criteria for pembrolizumab for stage III or IV resected melanoma – adjuvant

or

- ☐ The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor
  and
- ☐ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV
  and
- ☐ The individual meets initial application criteria for pembrolizumab for unresectable or metastatic melanoma

or

- ☐ The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor
  and
- ☐ The individual has received treatment with an immune checkpoint inhibitor for unresectable or metastatic melanoma
  and
- ☐ The individual meets renewal criteria for pembrolizumab for unresectable or metastatic melanoma

Note:

a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition

b) Initiating treatment within 13 weeks of complete surgical resection means either 13 weeks after resection (primary or lymphadenectomy) or 13 weeks prior to the scheduled date of the resection (primary or lymphadenectomy)

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

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Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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Pembrolizumab *- continued*

Initial application — stage III or IV resected melanoma - adjuvant
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 individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a)

and

- ☐ Adjuvant treatment with pembrolizumab is required

and

- ☐ The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma

and

- ☐ Treatment must be in addition to complete surgical resection

and

- ☐ Treatment must be initiated within 13 weeks of complete surgical resection, unless delay is necessary due to post-surgery recovery (see note b)

and

- ☐ Pembrolizumab must be administered as monotherapy

and

- ☐ The individual has ECOG performance score 0-2

and

- ☐ Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent)

Note:

a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition

b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)

I confirm 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 — stage III or IV resected melanoma - adjuvant

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)

- ☐ No evidence of disease recurrence
- **and** ☐ Pembrolizumab must be administered as monotherapy
- **and** ☐ Pembrolizumab to be administered at a fixed dose of 200 mg every three weeks (or equivalent) for a maximum of 12 months total treatment course, including any systemic neoadjuvant treatment
- **and** ☐ Treatment to be discontinued at signs of disease recurrence or at completion of 12 months total treatment course (equivalent to 18 cycles at a dose of 200 mg every 3 weeks), including any systemic neoadjuvant treatment

or

- ☐ The individual has received adjuvant treatment with an immune checkpoint inhibitor
- **and** ☐ The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV
- **and** ☐ The individual meets initial application criteria for pembrolizumab for unresectable or metastatic melanoma

or

- ☐ The individual has received adjuvant treatment with an immune checkpoint inhibitor
- **and** ☐ The individual has received treatment with an immune checkpoint inhibitor for unresectable or metastatic melanoma
- **and** ☐ The individual meets renewal criteria for pembrolizumab for unresectable or metastatic melanoma

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 — unresectable or metastatic melanoma
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 individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV

and

- ☐ Baseline measurement of overall tumour burden is documented clinically and radiologically

and

- ☐ The individual has ECOG performance score of 0-2

and

- ☐ The individual has not received funded nivolumab

or

- ☐ The individual has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance

and

- ☐ The cancer did not progress while the individual was on nivolumab

and

- ☐ The individual has been diagnosed in the metastatic or unresectable stage III or IV setting

or

- ☐ The individual did not receive treatment in the perioperative setting with a PD-1/PD-L1 inhibitor

or

- ☐ The individual received treatment in the perioperative setting with a PD-1/PD-L1 inhibitor

and

- ☐ The individual did not experience disease recurrence while on treatment with that PD-1/PD-L1 inhibitor

and

- ☐ The individual did not experience disease recurrence within six months of completing perioperative treatment with a PD-1/PD-L1 inhibitor

I confirm 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, less than 24 months on treatment

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 individual's disease has had a complete response to treatment
  - **or**
- ☐ The individual's disease has had a partial response to treatment
  - **or**
- ☐ The individual has stable disease

and

☐ Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period

or

☐ The individual has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression

and

☐ The individual has signs of disease progression

and

☐ Disease has not progressed during previous treatment with pembrolizumab

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 relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ The individual has been on treatment for more than 24 months

and

☐ The individual's disease has had a complete response to treatment

or

☐ The individual's disease has had a partial response to treatment

or

☐ The individual has stable disease

and

☐ Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period

or

☐ The individual has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression

and

☐ The individual has signs of disease progression

and

☐ Disease has not progressed during previous treatment with pembrolizumab

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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, ROS-1 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, ROS-1 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

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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.

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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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: .....

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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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)

- ☐ Patient's disease has had a complete response to treatment
- **or** ☐ Patient's disease has had a partial response to treatment
- **or** ☐ Patient has stable disease

and ☐ No evidence of disease progression

and ☐ Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent)

and ☐ Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

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)

- ☐ Individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment
- **or**
  - ☐ Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer
  - **or** ☐ Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer
  - **and** ☐ Individual is treated with palliative intent
  - **and** ☐ Individual has not previously received funded treatment with pembrolizumab for MSI-H/dMMR advanced colorectal cancer
  - **and** ☐ Individual has an ECOG performance score of 0-2
  - **and** ☐ Baseline measurement of overall tumour burden is documented clinically and radiologically
  - **and** ☐ Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks

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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)

☐ Individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment

or

☐ Individual has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy

and

☐ Individual is ineligible for autologous stem cell transplant

or

☐ Individual has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant

and

☐ Individual has not previously received funded pembrolizumab for relapsed/refractory Hodgkin lymphoma

and

☐ Pembrolizumab to be administered at doses no greater than 200 mg once every 3 weeks

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)

☐ Patient has received a partial or complete response to pembrolizumab

and

☐ Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks)

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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

and

- ☐ Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks

or

- ☐ Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks

and

☐ Treatment with durvalumab to cease upon signs of disease progression

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

- ☐ Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks

or

- ☐ Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks

and

☐ Treatment with durvalumab to cease upon signs of disease progression

and

☐ Total continuous treatment duration must not exceed 12 months

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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, ROS-1 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)

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

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Atezolizumab *- continued*

Initial application — unresectable hepatocellular carcinoma
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Patient is currently on treatment with atezolizumab and met all remaining criteria prior to commencing treatment

or

☐ Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma

and

☐ Patient has preserved liver function (Child-Pugh A)

and

☐ Transarterial chemoembolisation (TACE) is unsuitable

and

☐ Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma

or

☐ Patient received funded lenvatinib before 1 March 2025

or

☐ Patient has experienced treatment-limiting toxicity from treatment with lenvatinib

and

☐ No disease progression since initiation of lenvatinib

and

☐ Patient has an ECOG performance status of 0-2

and

☐ To be given in combination with bevacizumab

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

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Ipilimumab

Initial application — stage III or IV resectable melanoma
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 individual is currently on treatment with ipilimumab for neoadjuvant treatment of resectable stage IIIB, IIIC, IIID or IV melanoma and met all remaining criteria prior to commencing treatment

or

- ☐ The individual has resectable stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note)

and

- ☐ The individual has not received prior funded systemic treatment in the perioperative setting for their stage IIIB, IIIC, IIID or IV melanoma

and

- ☐ The individual has ECOG performance score 0-2

and

- ☐ Treatment must be prior to complete surgical resection

and

- ☐ Neoadjuvant ipilimumab must be administered in combination with nivolumab

and

- ☐ Ipilimumab to be administered for maximum of two cycles prior to surgical resection

Note:

a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition.

b) Disease must be completely resectable and amenable to curative intent surgery, including stage IV disease.

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

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Ipilimumab *- continued*

Initial application — renal cell carcinoma
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ The patient is currently on treatment with ipilimumab and met all remaining criteria prior to commencing treatment

or

☐ The patient has metastatic renal cell carcinoma

and

☐ The patient is treatment naive

and

☐ The patient has ECOG performance status 0-2

and

☐ The disease is predominantly of clear cell histology

and

☐ The patient has sarcomatoid histology

or

☐ Haemoglobin levels less than the lower limit of normal

or

☐ Corrected serum calcium level greater than 10 mg/dL (2.5 mmol/L)

or

☐ Neutrophils greater than the upper limit of normal

or

☐ Platelets greater than the upper limit of normal

or

☐ Interval of less than 1 year from original diagnosis to the start of systemic therapy

or

☐ Karnofsky performance score of less than or equal to 70

and

☐ Ipilimumab is to be used at a maximum dose of 1 mg/kg for up to four cycles in combination with nivolumab.

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Tacrolimus

Initial application — organ transplant
Applications only from a relevant specialist. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

- ☐ The individual is an organ transplant recipient

or

- ☐ The individual is receiving induction therapy for an organ transplant

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)

- ☐ Patient requires long-term systemic immunosuppression

and

- ☐ Ciclosporin has been trialled and discontinued treatment because of unacceptable side effects or inadequate clinical response

or

- ☐ Patient is a child with nephrotic syndrome*

Note: Indications marked with * are unapproved indications

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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
- Leukoencepthalopathy; 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)

☐ Patient has severe non-malignant lymphovascular malformation*

and

☐ Malformations are not adequately controlled by sclerotherapy and surgery

or

☐ Malformations are widespread/extensive and sclerotherapy and surgery are not considered clinically appropriate

or

☐ Sirolimus is to be used to reduce malformation prior to consideration of surgery

and

☐ Patient is being treated by a specialist lymphovascular malformation multi-disciplinary team

and

☐ Patient has measurable disease as defined by RECIST version 1.1 (see Note)

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

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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

or

☐ Vigabatrin has been trialled and has not adequately controlled seizures

and

☐ Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least two of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note)

or

☐ Vigabatrin is contraindicated

and

☐ Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least three of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note)

and

☐ Seizures have a significant impact on quality of life

and

☐ Patient has been assessed and surgery is considered inappropriate for this patient, or the patient has been assessed and would benefit from mTOR inhibitor treatment prior to surgery

Note: Those of childbearing 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 4 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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SA2599 - Upadacitinib

Crohn's disease - adult - Initial application 380
Crohn's disease - adult - Renewal 381
Crohn's disease - children* - Initial application 381
Crohn's disease - children* - Renewal 381
Rheumatoid Arthritis - Renewal 379
Rheumatoid Arthritis (previously treated with adalimumab or etanercept) - Initial application 379
Atopic dermatitis - Initial application 380
Atopic dermatitis - Renewal 380
Ulcerative colitis - Initial application 382
Ulcerative colitis - Renewal 382

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

Initial application — Rheumatoid Arthritis (previously treated with adalimumab or etanercept)
Applications from any relevant practitioner. Approvals valid for 7 months.
Prerequisites(tick boxes where appropriate)

- ☐ The individual has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis

and

- ☐ The individual has experienced intolerable side effects with adalimumab and/or etanercept

or

- ☐ The individual has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis

and

- ☐ Rituximab is not clinically appropriate

or

- ☐ The individual is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor

or

- ☐ The individual has been started on rituximab for rheumatoid arthritis in a Health NZ Hospital

and

- ☐ The individual has experienced intolerable side effects with rituximab

or

- ☐ At four months following the initial course of rituximab the individual has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis

Renewal — Rheumatoid Arthritis

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

Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ Following 6 months' initial treatment, the individual has experienced at least a 50% decrease in active joint count from baseline

or

- ☐ On subsequent reapplications, the individual has experienced at least a continuing 30% improvement in active joint count from baseline

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)

Reg No: .....

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Upadacitinib *- continued*

Initial application — atopic dermatitis
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Individual is currently on treatment with upadacitinib for atopic dermatitis and met all remaining criteria prior to commencing treatment

or

☐ Individual has moderate to severe atopic dermatitis, severity as defined by an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 or a Dermatology Life Quality Index (DLQI) score of greater than or equal to 10

and

☐ Individual has received insufficient benefit from topical therapy (including topical corticosteroids or topical calcineurin inhibitors) for a 28-day trial within the last 6 months, unless contraindicated to all

and

☐ Individual has trialled and received insufficient benefit from at least one systemic therapy for a minimum of three months (eg ciclosporin, azathioprine, methotrexate or mycophenolate mofetil), unless contraindicated to all

and

☐ An EASI assessment or DLQI assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course

and

☐ The most recent EASI or DQLI assessment is no more than 1 month old at the time of application

Renewal — atopic dermatitis

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

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

☐ Individual has received a 75% or greater reduction in EASI score (EASI 75) as compared to baseline EASI prior to commencing upadacitinib

or

☐ Individual has received a DLQI improvement of 4 or more as compared to baseline DLQI prior to commencing upadacitinib

Initial application — Crohn's disease - adult
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ Individual is currently on treatment with upadacitinib for Crohn's disease and met all remaining criteria prior to commencing treatment

or

☐ Individual has active Crohn's disease

and

☐ Individual has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

☐ Individual meets the initiation criteria for prior biologic therapies for Crohn's disease

and

☐ Other biologic therapies for Crohn's disease are contraindicated

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Upadacitinib *- continued*

Renewal — Crohn's disease - adult

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 when the individual was initiated on biologic therapy

or

- ☐ HBI score has reduced by 3 points from when individual was initiated on biologic therapy

or

- ☐ CDAI score is 150 or less

or

- ☐ HBI score is 4 or less

or

- ☐ The individual has experienced an adequate response to treatment, but CDAI score cannot be assessed

Initial application — Crohn's disease - children*

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

Prerequisites(tick boxes where appropriate)

- ☐ Individual is currently on treatment with upadacitinib for Crohn's disease and met all remaining criteria prior to commencing treatment

or

- ☐ Child has active Crohn's disease

and

- ☐ Child has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

- ☐ Child meets the initiation criteria for prior biologic therapies for Crohn's disease

and

- ☐ Other biologic therapies for Crohn's disease are contraindicated

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 child was initiated on treatment

or

- ☐ PCDAI score is 15 or less

or

- ☐ The child has experienced an adequate response to treatment, but PCDAI score cannot be assessed

Note: Indications marked with * are unapproved indications.

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

Initial application — ulcerative colitis
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ Individual is currently on treatment with upadacitinib for ulcerative colitis and met all remaining criteria prior to commencing treatment

or

- ☐ Individual has active ulcerative colitis

and

- ☐ Individual has had an initial approval for prior biologic therapy for ulcerative colitis and has experienced intolerable side effects or insufficient benefit to meet renewal criteria

or

- ☐ Individual meets the initiation criteria for prior biologic therapies for ulcerative colitis

and

- ☐ Other biologic therapies for ulcerative colitis are contraindicated

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 individual was initiated on treatment

or

- ☐ PUCAI score has reduced by 10 points or more from the PUCAI score when the individual was initiated on treatment

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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 without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Supply for anticipated emergency treatment of laryngeal/oro-pharyngeal or severe abdominal attacks of acute hereditary angioedema (HAE) for patients with confirmed diagnosis of C1-esterase inhibitor deficiency

and

☐ The patient has undergone product training and has agreed upon an action plan for self-administration

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APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA1367
October 2026

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

- ☐ RAST or skin test positive

and

- ☐ Patient has had severe generalised reaction to the sensitising agent

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

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Long-Acting Muscarinic Antagonists with Long-Acting Beta-Adrenoceptor Agonists

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

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

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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)

☐ Patient has a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible

and

☐ Patient is currently receiving an inhaled corticosteroid with long acting beta-2 agonist (ICS/LABA) or a long acting muscarinic antagonist with long acting beta-2 agonist (LAMA/LABA)

and

Clinical criteria:

☐ Patient has a COPD Assessment Test (CAT) score greater than 10

or

☐ Patient has had 2 or more exacerbations in the previous 12 months

or

☐ Patient has had one exacerbation requiring hospitalisation in the previous 12 months

or

☐ Patient has had an eosinophil count greater than or equal to 0.3 × 10^9 cells/L in the previous 12 months

or

☐ Patient is currently receiving multiple inhaler triple therapy (inhaled corticosteroid with long acting muscarinic antagonist and long acting beta-2 agonist – ICS/LAMA/LABA) and met at least one of the clinical criteria above prior to commencing multiple inhaler triple therapy

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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 × 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)

- ☐ Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist

and

- ☐ Forced vital capacity is between 50% and 90% predicted

and

- ☐ Pirfenidone is to be discontinued at disease progression (See Note)

and

- ☐ Pirfenidone is not to be used in combination with subsidised nintedanib

and

- ☐ The patient has not previously received treatment with nintedanib

or

- ☐ Patient has previously received nintedanib, but discontinued nintedanib within 12 weeks due to intolerance

or

- ☐ Patient has previously received nintedanib, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with nintedanib)

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)

- ☐ Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment

and

- ☐ Pirfenidone is not to be used in combination with subsidised nintedanib

and

- ☐ Pirfenidone is to be discontinued at disease progression (See Note)

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

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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)

- ☐ Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist

and

- ☐ Forced vital capacity is between 50% and 90% predicted

and

- ☐ Nintedanib is to be discontinued at disease progression (See Note)

and

- ☐ Nintedanib is not to be used in combination with subsidised pirfenidone

and

- ☐ The patient has not previously received treatment with pirfenidone

or

- ☐ Patient has previously received pirfenidone, but discontinued pirfenidone within 12 weeks due to intolerance

or

- ☐ Patient has previously received pirfenidone, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with pirfenidone)

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)

- ☐ Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment

and

- ☐ Nintedanib is not to be used in combination with subsidised pirfenidone

and

- ☐ Nintedanib is to be discontinued at disease progression (See Note)

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

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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)

☐ Patient has a confirmed diagnosis of cystic fibrosis

and

☐ Patient has previously undergone a trial with, or is currently being treated with, hypertonic saline

and

☐ Patient has required one or more hospital inpatient respiratory admissions in the previous 12 month period

or

☐ Patient has had 3 exacerbations due to CF, requiring oral or intravenous (IV) antibiotics in the previous 12 month period

or

☐ Patient has had 1 exacerbation due to CF, requiring oral or IV antibiotics in the previous 12 month period and a Brasfield score of < 22/25

or

☐ Patient has a diagnosis of allergic bronchopulmonary aspergillosis (ABPA)

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

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

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Ivacaftor

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Patient has been diagnosed with cystic fibrosis

and

☐ Patient has two cystic fibrosis-causing mutations in the cystic fibrosis transmembrane regulator (CFTR) gene (one from each parental allele)

or

☐ Patients must have a sweat chloride value of at least 60 mmol/L

and

☐ Patient has a mutation responsive to ivacaftor (see note)

and

☐ Treatment with ivacaftor must be given concomitantly with standard therapy for this condition

and

☐ The dose of ivacaftor will not exceed one tablet or one sachet twice daily

Note: Mutations listed in Table 3 of the Food and Drug Administration (FDA) Ivacaftor prescribing information https://www.accessdata.fda.gov/drugsatfda_docs/lab

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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)

☐ Patient has been diagnosed with cystic fibrosis

and

☐ Patient has two cystic fibrosis-causing mutations in the cystic fibrosis transmembrane regulator (CFTR) gene (one from each parental allele)

or

☐ Patient has a sweat chloride value of at least 60 mmol/L

and

☐ Patient has a heterozygous or homozygous F508del mutation

or

☐ Patient has a mutation responsive to elexacaftor/tezacaftor/ivacaftor (see note)

and

☐ The treatment must be the sole funded CFTR modulator therapy for this condition

and

☐ Treatment with elexacaftor/tezacaftor/ivacaftor must be given concomitantly with standard therapy for this condition

Note: Eligible mutations are listed in the Food and Drug Administration (FDA) Trikafta prescribing information https://www.accessdata.fda.gov/drugsatfda_docs/lab

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Vanzacaftor with tezacaftor and deutivacaftor

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Patient has been diagnosed with cystic fibrosis

and

☐ Patient has two cystic fibrosis-causing mutations in the cystic fibrosis transmembrane regulator (CFTR) gene (one from each parental allele)

or

☐ Patient has a sweat chloride value of at least 60 mmol/L

and

☐ Patient has a heterozygous or homozygous F508del mutation

or

☐ Patient has a mutation responsive to vanzacaftor/tezacaftor/deutivacaftor (see note)

and

☐ The treatment must be the sole funded CFTR modulator therapy for this condition

and

☐ Treatment with vanzacaftor/tezacaftor/deutivacaftor must be given concomitantly with standard therapy for this condition

Note: Eligible mutations are listed in the in the Food and Drug Administration (FDA) Alyftrek prescribing information https://www.accessdata.fda.gov/drugsatfda_d

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Sensory Organs

APPLICANT (stamp or sticker acceptable)

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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

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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)

- ☐ Patient's vision is stable or has improved (prescriber determined)

and

- ☐ Patient is of child bearing potential and has not yet completed a family

and

- ☐ Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year

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

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Reg No:	First Names:	First Names: .....
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Address:	DOB:	Address: .....
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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)

☐ Patient has severe inflammation
and
☐ 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

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA2644
October 2026

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
Reg No:	First Names:	First Names: .....
Name:	Surname:	Surname: .....
Address:	DOB:	Address: .....
.....	Address:	.....
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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)

- ☐ Patient has to use an unpreserved solution due to an allergy to the preservative

or

- ☐ Patient wears soft contact lenses

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: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA2431
October 2026

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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Preservative Free Ocular Lubricants

Initial application
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ Confirmed diagnosis by slit lamp or Schirmer test of severe secretory dry eye

and

☐ Patient is using eye drops more than four times daily on a regular basis

or

☐ Patient has had a confirmed allergic reaction to preservative in eye drop

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

Various

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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Deferiprone

Initial application
Applications only from a haematologist. Approvals valid without further renewal unless notified.
Prerequisites(tick boxes where appropriate)

☐ The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia

or

☐ 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.

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: 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: .....
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Deferasirox

Initial application
Applications only from a haematologist. Approvals valid for 2 years.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia

and

- ☐ Deferasirox is to be given at a daily dose not exceeding 40 mg/kg/day

and

- ☐ Treatment with maximum tolerated doses of deferiprone monotherapy or deferiprone and desferrioxamine combination therapy have proven ineffective as measured by serum ferritin levels, liver or cardiac MRI T2*

or

- ☐ Treatment with deferiprone has resulted in severe persistent vomiting or diarrhoea

or

- ☐ Treatment with deferiprone has resulted in arthritis

or

- ☐ Treatment with deferiprone is contraindicated due to a history of agranulocytosis (defined as an absolute neutrophil count (ANC) of < 0.5 cells per µL) or recurrent episodes (greater than 2 episodes) of moderate neutropenia (ANC 0.5 - 1.0 cells per µL)

Renewal

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

Applications only from a haematologist. Approvals valid for 2 years.
Prerequisites(tick boxes where appropriate)

- ☐ For the first renewal following 2 years of therapy, the treatment has been tolerated and has resulted in clinical improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels

or

- ☐ For subsequent renewals, the treatment has been tolerated and has resulted in clinical stability or continued improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

Special Foods

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA1930
October 2026

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

Address: .....

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REFERRER Reg No: .....

First Names: .....

Surname: .....

Address: .....

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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: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: 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: .....
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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)

☐ 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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA1376
October 2026

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

Address: .....

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REFERRER Reg No: .....

First Names: .....

Surname: .....

Address: .....

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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 .....

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA2204
October 2026

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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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.

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: 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: .....
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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.

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA1095
October 2026

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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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.

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA2205
October 2026

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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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 .....

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: 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: .....
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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.

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: 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: .....
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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.....

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA1379
October 2026

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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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)

☐ Child is aged one to ten years

and

☐ The child is being fed via a tube or a tube is to be inserted for the purposes of feeding

or

☐ Any condition causing malabsorption

or

☐ Faltering growth in an infant/child

or

☐ Increased nutritional requirements

or

☐ The child is being transitioned from TPN or tube feeding to oral feeding

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 Health New Zealand, Private Bag 3015, Wanganui – email: 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: .....
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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.....

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: 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: .....
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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)

☐ Malabsorption
or
☐ Short bowel syndrome
or
☐ Enterocutaneous fistulas
or
☐ Eosinophilic oesophagitis
or
☐ Inflammatory bowel disease
or
☐ 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)

☐ 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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

Address: .....

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REFERRER Reg No: .....

First Names: .....

Surname: .....

Address: .....

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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)

☐ Child aged one to eight years
and
☐ 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)

☐ 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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

SA1859 - Standard Supplements

Adults - Initial application 421
Adults - Renewal 422
Children - exclusive enteral nutrition for Crohn's disease - Initial application 420
Children - exclusive enteral nutrition for Crohn's disease - Renewal 421
Children - indications other than exclusive enteral nutrition for Crohn's disease - Initial application 420
Children - indications other than exclusive enteral nutrition for Crohn's disease - Renewal 420
Chronic disease OR tube feeding for patients who have previously been funded under Special Authority forms SA0702 or SA0583 - Renewal 425
Long-term medical condition - Initial application 424
Short-term medical condition - Initial application 422
Short-term medical condition - Renewal 423

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

Address: .....

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REFERRER Reg No: .....

First Names: .....

Surname: .....

Address: .....

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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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
Reg No:	First Names:	First Names: .....
Name:	Surname:	Surname: .....
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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)

☐ 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

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)

Patient is Malnourished

☐ Patient has a body mass index (BMI) of less than 18.5 kg/m^2

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^2 and unintentional weight loss greater than 5% within the last 3-6 months

and

Patient has not responded to first-line dietary measures over a 4 week period by:

☐ Increasing their food intake frequency (eg snacks between meals)

or

☐ Using high-energy foods (e.g. milkshakes, full fat milk, butter, cream, cheese, sugar etc)

or

☐ Using over the counter supplements (e.g. Complan)

and

☐ 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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
Reg No:	First Names:	First Names: .....
Name:	Surname:	Surname: .....
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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^2

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^2 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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

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REFERRER Reg No: .....

First Names: .....

Surname: .....

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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)

- ☐ Is being fed via a nasogastric tube

or

- ☐ Malignancy and is considered likely to develop malnutrition as a result

or

- ☐ Has undergone 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 Health New Zealand, Private Bag 3015, Wanganui – email: 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: .....
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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)

- ☐ 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

- ☐ Cystic Fibrosis

or

- ☐ Liver disease

or

- ☐ Chronic Renal failure

or

- ☐ Inflammatory bowel disease

or

- ☐ Chronic obstructive pulmonary disease with hypercapnia

or

- ☐ Short bowel syndrome

or

- ☐ Bowel fistula

or

- ☐ Severe chronic neurological conditions

or

- ☐ Epidermolysis bullosa

or

- ☐ AIDS (CD4 count < 200 cells/mm^3)

or

- ☐ Chronic pancreatitis

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

Signed: ..... Date: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

Address: .....

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REFERRER Reg No: .....

First Names: .....

Surname: .....

Address: .....

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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)

- ☐ 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

- ☐ Cystic Fibrosis

or

- ☐ Liver disease

or

- ☐ Chronic Renal failure

or

- ☐ Inflammatory bowel disease

or

- ☐ Chronic obstructive pulmonary disease with hypercapnia

or

- ☐ Short bowel syndrome

or

- ☐ Bowel fistula

or

- ☐ 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: .....

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA1195
October 2026

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

Surname: .....

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REFERRER Reg No: .....

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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 Health New Zealand, Private Bag 3015, Wanganui – email: 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: .....
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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)

☐ 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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
Reg No:	First Names:	First Names: .....
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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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA1729
October 2026

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

- ☐ Gluten enteropathy has been diagnosed by biopsy

or

- ☐ 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: .....
Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)

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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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
Reg No:	First Names:	First Names: .....
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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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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

- ☐ 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

or

- ☐ 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: .....

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: 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: .....
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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

or

- ☐ 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: .....

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)

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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: .....

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)

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PATIENT NHI: .....

First Names: .....

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First Names: .....

Surname: .....

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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

or

- ☐ 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: .....

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

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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 malsorption

or

☐ Cystic fibrosis

or

☐ Proven fat malabsorption

or

☐ Severe intestinal motility disorders causing significant malabsorption

or

☐ Intestinal failure

or

☐ For step down from Amino Acid Formula

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: .....

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

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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)

☐ An assessment as to whether the infant can be transitioned to a cows milk protein or soy infant formula has been undertaken

and

☐ The outcome of the assessment is that the infant continues to require an extensively hydrolysed infant formula

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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA1953
October 2026

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

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PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

Address: .....

.....

.....

.....

REFERRER Reg No: .....

First Names: .....

Surname: .....

Address: .....

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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 Health New Zealand, Private Bag 3015, Wanganui – email: 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:	.....
.....	.....	.....
.....	.....	.....

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)

- ☐ Patient is fluid restricted or volume intolerant and has been diagnosed with faltering growth

and

- ☐ Patient is under the care of a paediatrician or dietitian who has recommended treatment with a high energy infant formula

and

- ☐ 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)

- ☐ Patient continues to be fluid restricted or volume intolerant and has faltering growth

and

- ☐ Patient is under the care of a hospital paediatrician or dietitian who has recommended treatment with a high energy infant formula

and

- ☐ 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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICATION FOR SUBSIDY BY SPECIAL AUTHORITY

Form SA1197
October 2026

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
Reg No:	First Names:	First Names: .....
Name:	Surname:	Surname: .....
Address:	DOB:	Address: .....
.....	Address:	.....
.....	.....	.....
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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 Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

Index of form numbers

SA0906 Topical local anaesthetics 147
SA0928 Finasteride 90
SA0987 Aprepitant 152
SA1032 Tamsulosin 91
SA1036 Multivitamins 40
SA1083 Potassium Citrate 92
SA1095 Diabetic products 411
SA1098 Paediatric Product For Children Awaiting Liver Transplant 413
SA1099 Paediatric Product For Children With Chronic Renal Failure 414
SA1101 Renal Products 416
SA1106 Food Thickeners 428
SA1110 Infant Formulae - For Williams Syndrome 431
SA1139 Teriparatide 141
SA1195 High Calorie Products 426
SA1196 Paediatric enteral feed with fibre 0.75 kcal/ml 418
SA1197 High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate 440
SA1199 Propylthiouracil 96
SA1289 Capsaicin 140
SA1320 Diazoxide 10
SA1321 Hydralazine 63
SA1322 Itraconazole 115
SA1327 Propranolol 60
SA1329 Glyceryl trinitrate Oint 0.2% 8
SA1331 Sulfadiazine 112
SA1355 Minocycline hydrochloride Tab 50 mg 109
SA1359 Fluconazole oral liquid 114
SA1367 Bee or wasp venom allergy treatment 386
SA1376 Carbohydrate and Fat 408
SA1377 Specialised And Elemental Products 417
SA1379 Paediatric Products 415
SA1386 Phenobarbitone 162
SA1403 Riluzole 146
SA1408 Naltrexone 172
SA1461 Rifaximin 9
SA1474 Midodrine 59
SA1480 Deferiprone 403
SA1492 Deferasirox 404
SA1524 Protein 410
SA1546 Multivitamin renal 41
SA1557 Extensively hydrolysed formula 436
SA1596 Siltuximab 252
SA1599 Sodium benzoate 25
SA1605 Ledipasvir with sofosbuvir 4
SA1623 Idursulfase 27
SA1680 Dexamethasone 700 mcg ocular implants 397
SA1683 Azithromycin 107
SA1684 Primaquine 120
SA1685 Lamivudine 123
SA1689 Paromomycin 113
SA1691 Methylnaltrexone bromide 21
SA1695 Laronidase 28
SA1698 Paediatric oral/enteral feed 1 kcal/ml 439
SA1715 Prednisolone sodium phosphate 399
SA1720 Vitabdeck 39
SA1725 Mercaptopurine 179
SA1728 Eplerenone 61
SA1729 Gluten Free Foods 429
SA1740 Moxifloxacin 110
SA1743 Eltrombopag 47
SA1845 Varenicline tartrate 173
SA1857 Clarithromycin 108
SA1859 Standard Supplements 420
SA1870 Alectinib 202
SA1890 Ruxolitinib 201
SA1895 Fulvestrant 222
SA1930 Carbohydrate 406
SA1953 Enteral liquid peptide formula 438
SA1963 Benzbromarone 143
SA1970 Pimecrolimus 88
SA1978 Dornase Alfa 392
SA1986 Alglucosidase Alfa 26
SA1987 Betaine 29
SA1988 Galsulfase 23
SA1989 Sapropterin dihydrochloride 30
SA1990 Sodium phenylbutyrate 24
SA1998 Hyoscine (Scopolamine) 151
SA2012 Nintedanib 391
SA2013 Pirfenidone 390
SA2024 Acitretin 87
SA2032 Somatropin 98
SA2034 Pegylated Interferon alfa-2A 134
SA2039 Coenzyme Q10 31
SA2040 Levocarnitine 32
SA2041 Riboflavin 33
SA2042 Arginine 34
SA2043 Taurine 35
SA2053 Sodium picosulfate 22
SA2070 Cabergoline 104
SA2074 Tacrolimus Ointment 86
SA2088 Vigabatrin 148
SA2092 Amino acid formula 432
SA2118 Abiraterone acetate 220
SA2137 Taliglucerase alfa 38
SA2139 Antiretrovirals 131
SA2151 Benralizumab 324
SA2157 Adalimumab (Humira - Alternative brand) 238
SA2163 Olaparib 189
SA2166 Tolvaptan 62
SA2167 Paliperidone palmitate 157
SA2170 Cinacalcet 94
SA2174 Nusinersen 164
SA2182 Ustekinumab 325
SA2183 Vedolizumab 328
SA2185 Adrenaline 384
SA2203 Risdiplam 165
SA2204 Fat 409
SA2205 Fat Modified Products 412
SA2234 Linezolid 121
SA2244 Bedaquiline 122
SA2267 Lacosamide 149
SA2268 Stiripentol 150
SA2269 Gemtuzumab ozogamicin 323
SA2270 Sirolimus (Rapamune) 373
SA2272 Emicizumab 49
SA2273 Ocrelizumab 160
SA2274 Multiple Sclerosis 158
SA2276 Pertuzumab 253
SA2293 Trastuzumab (Herzuma) 333
SA2301 Nilotinib 200
SA2302 Sacubitril with valsartan 58
SA2324 Trientine 36
SA2325 Niraparib 192
SA2326 Fluticasone furoate with umeclidinium and vilanterol 388
SA2331 Mepolizumab 304
SA2342 Midostaurin 204
SA2345 Palbociclib (Ibrance) 203
SA2353 Lenalidomide 193
SA2354 Pomalidomide 194
SA2356 Thalidomide 181
SA2357 Foods and Supplements For Inborn Errors Of Metabolism 430
SA2367 Insulin pump with algorithm 14
SA2383 Posaconazole 118
SA2384 Voriconazole 116
SA2385 Dasatinib 195
SA2394 Ferric carboxymaltose 42
SA2395 Aripiprazole 155
SA2396 Paliperidone depot injection 156
SA2397 Risperidone 153
SA2398 Bendamustine hydrochloride 177
SA2401 Cetuximab 256
SA2406 Fosfomycin 138
SA2418 Osimertinib 209
SA2420 Trastuzumab deruxtecan 336
SA2421 Budesonide with glycopyrronium and eformoterol 389
SA2422 Erlotinib 196
SA2423 Gefitinib 199
SA2424 Trastuzumab emtansine 285

INDEX OF FORM NUMBERS

SA2425 Durvalumab 367
SA2431 Preservative Free Ocular Lubricants 401
SA2441 Denosumab 142
SA2442 Lenvatinib 206
SA2445 Long-acting Somatostatin Analogues 223
SA2448 Ursodeoxycholic Acid 19
SA2451 Modafinil 170
SA2453 Bevacizumab 337
SA2455 Tacrolimus 372
SA2458 Axitinib 211
SA2460 Inotuzumab ozogamicin 340
SA2479 Azacitidine 180
SA2489 Tocilizumab 278
SA2495 Ribociclib 205
SA2511 Ivermectin 84
SA2512 Albendazole 106
SA2514 Valganciclovir 124
SA2520 Emtricitabine with tenofovir disoproxil 129
SA2523 Melatonin 163
SA2524 Rivastigmine patches 171
SA2525 Adalimumab (Amgevita) 307
SA2532 Entrectinib 219
SA2533 Faricimab 341
SA2534 Pertuzumab with trastuzumab 343
SA2535 Budesonide - Cap 3 mg Controlled Release 6
SA2536 Insulin Pump Consumables 15
SA2537 Continuous glucose monitor (interoperable) 17
SA2538 Continuous glucose monitor (standalone) 16
SA2539 Hypoplastic and Haemolytic 45
SA2547 Crizotinib 212
SA2548 Dabrafenib 213
SA2549 Trametinib 216
SA2550 Aflibercept 257
SA2554 Long-Acting Muscarinic Antagonists with Long-Acting Beta-Adrenoceptor Agonists 387
SA2555 Febuxostat 144
SA2556 Ambrisentan 68
SA2557 Bosentan 64
SA2558 Sildenafil (Vedafil) 72
SA2559 Epoprostenol 78
SA2560 Iloprost 74
SA2561 Nitisinone 37
SA2584 Isotretinoin 82
SA2586 Olanzapine depot injection 154
SA2587 Dexamfetamine sulfate 167
SA2588 Lisdexamfetamine dimesilate 166
SA2591 Methylphenidate hydrochloride Extended Release 169
SA2592 Buprenorphine with naloxone 174
SA2593 Bortezomib 184
SA2596 Pazopanib 198
SA2597 Omalizumab 249
SA2598 Everolimus 376
SA2599 Upadacitinib 379
SA2613 Filgrastim 55
SA2614 Pegfilgrastim 56
SA2618 Pegaspargase 185
SA2619 Etanercept 226
SA2620 Infliximab 263
SA2622 Rituximab 235
SA2624 Secukinumab 259
SA2628 Enoxaparin sodium 53
SA2629 Brentuximab 331
SA2630 Atezolizumab 368
SA2631 Pembrolizumab 352
SA2635 Letermovir 127
SA2637 Ibrutinib 191
SA2639 Obinutuzumab 254
SA2640 Palivizumab 321
SA2642 Ipilimumab 370
SA2643 Nivolumab 344
SA2644 Pilocarpine – Eye drops 2% single dose 400
SA2648 Vanzacaftor with tezacaftor and deutivacaftor 395
SA2650 Ivacaftor 393
SA2652 Elexacaftor with tezacaftor, ivacaftor and ivacaftor 394
SA2678 Venetoclax 186
SA2683 Ticagrelor 50
SA2686 Temozolomide 182
SA2687 Sunitinib 197
SA2689 Rituximab 288
SA2690 Dulaglutide 11
SA2691 Liraglutide 12
SA2692 Empagliflozin; Empagliflozin with metformin hydrochloride 13
SA2720 Methylphenidate hydrochloride 168
SA2721 Icatibant 385

Index of titles

Abiraterone acetate (SA2118) 220
Acitretin (SA2024) 87
Adalimumab (Amgevita) (SA2525) 307
Adalimumab (Humira - Alternative brand) (SA2157) 238
Adrenaline (SA2185) 384
Aflibercept (SA2550) 257
Albendazole (SA2512) 106
Alectinib (SA1870) 202
Alglucosidase Alfa (SA1986) 26
Ambrisentan (SA2556) 68
Amino acid formula (SA2092) 432
Antiretrovirals (SA2139) 131
Aprepitant (SA0987) 152
Arginine (SA2042) 34
Aripiprazole (SA2395) 155
Atezolizumab (SA2630) 368
Axitinib (SA2458) 211
Azacitidine (SA2479) 180
Azithromycin (SA1683) 107
Bedaquiline (SA2244) 122
Bee or wasp venom allergy treatment (SA1367) 386
Bendamustine hydrochloride (SA2398) 177
Benralizumab (SA2151) 324
Benzbromarone (SA1963) 143
Betaine (SA1987) 29
Bevacizumab (SA2453) 337
Bortezomib (SA2593) 184
Bosentan (SA2557) 64
Brentuximab (SA2629) 331
Budesonide - Cap 3 mg Controlled Release (SA2535) 6
Budesonide with glycopyrronium and eformoterol (SA2421) 389
Buprenorphine with naloxone (SA2592) 174
Cabergoline (SA2070) 104
Capsaicin (SA1289) 140
Carbohydrate and Fat (SA1376) 408
Carbohydrate (SA1930) 406
Cetuximab (SA2401) 256
Cinacalcet (SA2170) 94
Clarithromycin (SA1857) 108
Coenzyme Q10 (SA2039) 31
Continuous glucose monitor (interoperable) (SA2537) 17
Continuous glucose monitor (standalone) (SA2538) 16
Crizotinib (SA2547) 212
Dabrafenib (SA2548) 213
Dasatinib (SA2385) 195
Deferasirox (SA1492) 404
Deferiprone (SA1480) 403
Denosumab (SA2441) 142
Dexamethasone 700 mcg ocular implants (SA1680) 397
Dexamfetamine sulfate (SA2587) 167
Diabetic products (SA1095) 411
Diazoxide (SA1320) 10
Dornase Alfa (SA1978) 392
Dulaglutide (SA2690) 11
Durvalumab (SA2425) 367
Elexacaftor with tezacaftor, ivacaftor and ivacaftor (SA2652) 394
Eltrombopag (SA1743) 47
Emicizumab (SA2272) 49
Empagliflozin; Empagliflozin with metformin hydrochloride (SA2692) 13
Emtricitabine with tenofovir disoproxil (SA2520) 129
Enoxaparin sodium (SA2628) 53
Enteral liquid peptide formula (SA1953) 438
Entrectinib (SA2532) 219
Eplerenone (SA1728) 61
Epoprostenol (SA2559) 78
Erlotinib (SA2422) 196
Etanercept (SA2619) 226
Everolimus (SA2598) 376
Extensively hydrolysed formula (SA1557) 436
Faricimab (SA2533) 341
Fat Modified Products (SA2205) 412
Fat (SA2204) 409
Febuxostat (SA2555) 144
Ferric carboxymaltose (SA2394) 42
Filgrastim (SA2613) 55
Finasteride (SA0928) 90
Fluconazole oral liquid (SA1359) 114
Fluticasone furoate with umeclidinium and vilanterol (SA2326) 388
Food Thickeners (SA1106) 428
Foods and Supplements For Inborn Errors Of Metabolism (SA2357) 430
Fosfomycin (SA2406) 138
Fulvestrant (SA1895) 222
Galsulfase (SA1988) 23
Gefitinib (SA2423) 199
Gemtuzumab ozogamicin (SA2269) 323
Gluten Free Foods (SA1729) 429
Glyceryl trinitrate Oint 0.2% (SA1329) 8
High Calorie Products (SA1195) 426
High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate (SA1197) 440
Hydralazine (SA1321) 63
Hyoscine (Scopolamine) (SA1998) 151
Hypoplastic and Haemolytic (SA2539) 45
Ibrutinib (SA2637) 191
Icatibant (SA2721) 385
Idursulfase (SA1623) 27
Iloprost (SA2560) 74
Infant Formulae - For Williams Syndrome (SA1110) 431
Infliximab (SA2620) 263
Inotuzumab ozogamicin (SA2460) 340
Insulin Pump Consumables (SA2536) 15
Insulin pump with algorithm (SA2367) 14
Ipilimumab (SA2642) 370
Isotretinoin (SA2584) 82
Itraconazole (SA1322) 115
Ivacaftor (SA2650) 393
Ivermectin (SA2511) 84
Lacosamide (SA2267) 149
Lamivudine (SA1685) 123
Laronidase (SA1695) 28
Ledipasvir with sofosbuvir (SA1605) 4
Lenalidomide (SA2353) 193
Lenvatinib (SA2442) 206
Letermovir (SA2635) 127
Levocarnitine (SA2040) 32
Linezolid (SA2234) 121
Liraglutide (SA2691) 12
Lisdexamfetamine dimesilate (SA2588) 166
Long-Acting Muscarinic Antagonists with Long-Acting Beta-Adrenoceptor Agonists (SA2554) 387
Long-acting Somatostatin Analogues (SA2445) 223
Melatonin (SA2523) 163
Mepolizumab (SA2331) 304
Mercaptopurine (SA1725) 179
Methylnaltrexone bromide (SA1691) 21
Methylphenidate hydrochloride Extended Release (SA2591) 169
Methylphenidate hydrochloride (SA2720) 168
Midodrine (SA1474) 59
Midostaurin (SA2342) 204
Minocycline hydrochloride Tab 50 mg (SA1355) 109
Modafinil (SA2451) 170
Moxifloxacin (SA1740) 110
Multiple Sclerosis (SA2274) 158
Multivitamin renal (SA1546) 41
Multivitamins (SA1036) 40
Naltrexone (SA1408) 172
Nilotinib (SA2301) 200
Nintedanib (SA2012) 391
Niraparib (SA2325) 192
Nitisinone (SA2561) 37
Nivolumab (SA2643) 344
Nusinersen (SA2174) 164
Obinutuzumab (SA2639) 254
Ocrelizumab (SA2273) 160
Olanzapine depot injection (SA2586) 154
Olaparib (SA2163) 189
Omalizumab (SA2597) 249
Osimertinib (SA2418) 209

INDEX OF TITLES

Paediatric Product For Children Awaiting Liver Transplant (SA1098) 413
Paediatric Product For Children With Chronic Renal Failure (SA1099) 414
Paediatric Products (SA1379) 415
Paediatric enteral feed with fibre 0.75 kcal/ml (SA1196) 418
Paediatric oral/enteral feed 1 kcal/ml (SA1698) 439
Palbociclib (Ibrance) (SA2345) 203
Paliperidone depot injection (SA2396) 156
Paliperidone palmitate (SA2167) 157
Palivizumab (SA2640) 321
Paromomycin (SA1689) 113
Pazopanib (SA2596) 198
Pegaspargase (SA2618) 185
Pegfilgrastim (SA2614) 56
Pegylated Interferon alfa-2A (SA2034) 134
Pembrolizumab (SA2631) 352
Pertuzumab (SA2276) 253
Pertuzumab with trastuzumab (SA2534) 343
Phenobarbitone (SA1386) 162
Pilocarpine – Eye drops 2% single dose (SA2644) 400
Pimecrolimus (SA1970) 88
Pirfenidone (SA2013) 390
Pomalidomide (SA2354) 194
Posaconazole (SA2383) 118
Potassium Citrate (SA1083) 92
Prednisolone sodium phosphate (SA1715) 399
Preservative Free Ocular Lubricants (SA2431) 401
Primaquine (SA1684) 120
Propranolol (SA1327) 60
Propylthiouracil (SA1199) 96
Protein (SA1524) 410
Renal Products (SA1101) 416
Ribociclib (SA2495) 205
Riboflavin (SA2041) 33
Rifaximin (SA1461) 9
Riluzole (SA1403) 146
Risdiplam (SA2203) 165
Risperidone (SA2397) 153
Rituximab (SA2622) 235
Rituximab (SA2689) 288
Rivastigmine patches (SA2524) 171
Ruxolitinib (SA1890) 201
Sacubitril with valsartan (SA2302) 58
Sapropterin dihydrochloride (SA1989) 30
Secukinumab (SA2624) 259
Sildenafil (Vedafil) (SA2558) 72
Siltuximab (SA1596) 252
Sirolimus (Rapamune) (SA2270) 373
Sodium benzoate (SA1599) 25
Sodium phenylbutyrate (SA1990) 24
Sodium picosulfate (SA2053) 22
Somatropin (SA2032) 98
Specialised And Elemental Products (SA1377) 417
Standard Supplements (SA1859) 420
Stiripentol (SA2268) 150
Sulfadiazine (SA1331) 112
Sunitinib (SA2687) 197
Tacrolimus (SA2455) 372
Tacrolimus Ointment (SA2074) 86
Taliglucerase alfa (SA2137) 38
Tamsulosin (SA1032) 91
Taurine (SA2043) 35
Temozolomide (SA2686) 182
Teriparatide (SA1139) 141
Thalidomide (SA2356) 181
Ticagrelor (SA2683) 50
Tocilizumab (SA2489) 278
Tolvaptan (SA2166) 62
Topical local anaesthetics (SA0906) 147
Trametinib (SA2549) 216
Trastuzumab (Herzuma) (SA2293) 333
Trastuzumab deruxtecan (SA2420) 336
Trastuzumab emtansine (SA2424) 285
Trientine (SA2324) 36
Upadacitinib (SA2599) 379
Ursodeoxycholic Acid (SA2448) 19
Ustekinumab (SA2182) 325
Valganciclovir (SA2514) 124
Vanzacaftor with tezacaftor and deutivacaftor (SA2648) 395
Varenicline tartrate (SA1845) 173
Vedolizumab (SA2183) 328
Venetoclax (SA2678) 186
Vigabatrin (SA2088) 148
Vitabdeck (SA1720) 39
Voriconazole (SA2384) 116