

Pharmaceutical Management Agency New Zealand Pharmaceutical Schedule

Update

July 2022

Contents

Summary of Pharmac decisions effective 1 July 2022	3
Changes to General Rules	5
Fender News	6
ooking Forward	6
Sole Subsidised Supply (SSS) or Principal Supply Status (PSS) Products – Cumulative to July 2022	7
New Listings	19
Changes to Restrictions, Chemical Names and Presentations	20
Changes to Subsidy and Manufacturer's Price	36
Delisted Items	38
tems to be Delisted	39
ndex	40

Summary of Pharmac decisions EFFECTIVE 1 JULY 2022

New listings (page 19)

- Tenofovir disoproxil (Tenofovir Disoproxil Mylan) tab 245 mg (300.6 mg as a maleate)
- Emtricitabine with tenofovir disoproxil (Tenofovir Disoproxil Emtricitabine Mylan) tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a maleate) subsidy by endorsement; can be waived by Special Authority
- Metoclopramide hydrochloride (Baxter) inj 5 mg per ml, 2 ml ampoule
 Up to 5 inj available on a PSO
- Gemtuzumab ozogamicin (Mylotarg) inj 5 mg vial PCT only Specialist
 Special Authority
- Adalimumab (Humira) inj 20 mg per 0.2 ml prefilled syringe Special Authority

 Retail pharmacy
- Acetylcysteine (Martindale Pharma) inj 200 mg per ml, 10 ml ampoule

Changes to restrictions (pages 20-35)

- Docusate sodium with sennosides (Laxsol) tab 50 mg with sennosides 8 mg
 stat dispensing removed
- Taliglucerase alfa (Elelyso) inj 200 unit vial amended Special authority criteria
- Oxytocin with ergometrine maleate (Syntometrine) inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml ampoule – amended presentation description
- Cinacalcet (Cinacalcet Devatis) tab 30 mg brand switch fee removed
- Emtricitabine with tenofovir disoproxil tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a maleate) (Tenofovir Disoproxil Emtricitabine Mylan) and tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate) (Teva) amended Special authority criteria and addition of stat dispensing
- Antiretrovirals amended Special Authority criteria
- Nevirapine (Viramune Suspension) oral suspension 10 mg per ml, 240 ml OP

 addition of OP
- Nitrofurantoin (Macrobid) cap modified-release 100 mg addition of PSO and wastage claimable removed
- Entacapone (Comtan) tab 200 mg brand switch fee removed
- Cyclizine lactate (Hameln) inj 50 mg per ml, 1 ml ampoule amended presentation description
- Multiple Sclerosis Treatments amended Special Authority criteria
- Melatonin (Vigisom) tab modified-release 2 mg brand switch fee removed
- Azacitidine inj 100 mg vial (Azacitidine Dr Reddy's and Vidaza) and inj 1 mg for ECP (Baxter) – amended Special Authority criteria

Summary of Pharmac decisions - effective 1 July 2022 (continued)

- Adalimumab (Amgevita) inj 20 mg per 0.4 ml prefilled syringe, inj 40 mg per 0.8 ml prefilled pen and inj 40 mg per 0.8 ml prefilled syringe – amended Special Authority criteria
- Palivizumab (Synagis) inj 100 mg per ml, 1 ml vial amended Special Authority criteria
- Trastuzumab emtansine inj 100 mg vial and 160 mg vial (Kadcyla) and inj 1 mg for ECP (Baxter) – amended Special Authority criteria

Increased subsidy (page 36)

- Oxytocin with ergometrine maleate (Syntometrine) inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml ampoule
- Morphine hydrochloride (RA-Morph) oral liq 1 mg per ml, 200 ml

Decreased subsidy (pages 36-37)

- Calcitriol (Calcitriol-AFT) cap 0.25 mcg and 0.5 mcg
- Compound electrolytes (Electral) powder for oral soln
- Amiodarone hydrochloride tab 100 mg and 200 mg (Aratac) and inj 50 mg per ml, 3 ml ampoule (Max Health)
- Dimethicone lotn 4%, 200 ml OP (healthE Dimethicone 4% Lotion) and crm 5% pump bottle, 500 ml OP (healthE Dimethicone 5%)
- Fludrocortisone acetate (Florinef) tab 100 mcg
- Cefalexin (Cephalexin ABM) cap 500 mg
- Pramipexole hydrochloride (Ramipex) tab 0.25 mg and 1 mg
- Cyclizine lactate (Hameln) inj 50 mg per ml, 1 ml ampoule
- Buprenorphine with naloxone (Buprenorphine Naloxone BNM) tab 2 mg with naloxone 0.5 mg and 8 mg with naloxone 2 mg
- Mercaptopurine (Puri-nethol) tab 50 mg
- Montelukast (Montelukast Mylan) tab 4 mg, 5 mg and 10 mg
- Chloramphenicol (Devatis) eye oint 1%, 5 g OP
- Olopatadine (Olopatadine Teva) eye drops 0.1%, 5 ml OP

Changes to General Rules

We have amended some references in Community medicines and related products (Section B) and National Immunisation Schedule (Section I) to reflect the health system reforms that come into effect from 1 July 2022. There are corresponding amendments to the General Rules of the Pharmaceutical Schedule.

A summary of the changes to Sections B and I is provided below (only the relevant parts of criteria are shown).

Section B

Endorsement criteria for cefazolin injections

Only if prescribed for dialysis or cellulitis in accordance with a DHB Health NZ Hospital approved protocol and the prescription is endorsed accordingly

Special Authority criteria for naltrexone hydrochloride

2 Applicant works in or with a community Alcohol and Drug Service contracted to one of the District Health-Boards Health NZ or accredited against the New Zealand Alcohol and Other Drug Sector Standard or the National Mental Health Sector Standard.

Special Authority criteria for etanercept

Initial application — (adult-onset Still's disease)

1.1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital Health NZ Hospital inaccordance with the HML rules; and

Special Authority criteria for secukinumab

Initial application — severe chronic plaque psoriasis – second-line biologic

1 The patient has had an initial Special Authority approval for adalimumab or etanercept, or has trialled infliximab in a DHB hospital-Health NZ Hospital in accordance with the General Rules of the Pharmaceutical-Schedule, for severe chronic plaque psoriasis; and

Special Authority criteria for tocilizumab

Initial application — (Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept))

3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a DHB hospital Health NZ Hospital in accordance with the Section H rules; and

Initial application — (adult-onset Still's disease)

1.1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital Health NZ Hospital inaccordance with the General Rules of the Pharmaceutical Schedule: and

Special Authority criteria for upadacitinib

Initial application — (Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept))

3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a DHB hospital Health NZ Hospital in accordance with the Section H rules; and

Changes to General Rules (continued)

Section I

Influenza vaccine inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine)

B) Doctors are the only Contractors entitled to claim payment from the Funder for the supply of influenza vaccine inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine) to patients eligible under the above criteria for subsidised immunisation and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.

Influenza vaccine inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)

B) Contractors will be entitled to claim payment from the Funder for the supply of influenza vaccine to patients eligible under the above criteria pursuant to their contract with their DHB Health NZ for subsidised immunisation, and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.

Measles, mumps and rubella vaccine

B) Contractors will be entitled to claim payment from the Funder for the supply of measles, mumps and rubella vaccine to patients eligible under the above criteria pursuant to their contract with their DHB Health NZ for subsidised immunisation, and they may only do so in respect of the measles, mumps and rubella vaccine listed in the Pharmaceutical Schedule.

Tender News

Sole Subsidised Supply (SSS) or Principal Supply Status (PSS) changes – effective 1 August 2022

Chemical Name	Presentation; Pack size	PSS/ SSS	PSS/SSS brand (and supplier)
Ferrous fumarate with folic acid	Tab 310 mg (100 mg elemental) with folic acid 350 mcg; 100 tab pack	PSS	Ferro-F-Tabs (AFT)

Looking Forward

This section is designed to alert both pharmacists and prescribers to possible future changes to the Pharmaceutical Schedule. It may also assist pharmacists, distributors and wholesalers to manage stock levels.

Decisions for implementation 1 August 2022

- Durvalumab (Imfinzi) inj 50 mg per ml, 2.4 ml and 10 ml vial and inj 1 mg for ECP – new listing with Special Authority and PCT only
- Cefalexin (Flynn) grans for oral liq 25 mg per ml and 50 mg per ml
 new listing (previously delayed)
- Olaparib (Lynparza) tab 100 mg and 150 mg amend Special Authority

Generic Name	Presentation	Brand Name	Expiry Date*
Acarbose	Tab 50 mg & 100 mg	Accarb	2024
Aciclovir	Eye oint 3%, 4.5 g OP	ViruPOS	2024
Acitretin	Cap 10 mg & 25 mg	Novatretin	2023
Allopurinol	Tab 100 mg & 300 mg	DP-Allopurinol	2023
Ambrisentan	Tab 5 mg &10 mg	Ambrisentan Mylan	2023
Amitriptyline	Tab 10 mg, 25 mg & 50 mg	Arrow-Amitriptyline	2023
Amlodipine	Tab 2.5 mg, 5 mg & 10 mg	Vasorex	2023
Amorolfine	Nail soln 5%, 5 ml OP	MycoNail	2023
Amoxicillin	Grans for oral liq 125 mg per 5 ml Grans for oral liq 250 mg per 5 ml	Alphamox 125 Alphamox 250	2023
Amoxicillin with clavulanic acid	Tab 500 mg with clavulanic acid 125 mg	Curam Duo 500/125	5 2023
Anastrozole	Tab 1 mg	Anatrole	2023
Apomorphine hydrochloride	Inj 10 mg per ml, 5 ml ampoule Inj 10 mg per ml, 2 ml ampoule	Movapo	2023
Aprepitant	Cap 2 x 80 mg and 1 x 125 mg	Emend Tripack	2024
Aqueous cream	Crm, 500 g	GEM Aqueous Cream	2024
Atenolol	Tab 50 mg & 100 mg	Mylan Atenolol	2024
Atorvastatin	Tab 10 mg, 20 mg, 40 mg & 80 mg	Lorstat	2024
Atropine sulphate	Inj 600 mcg per ml, 1 ml ampoule Eye drops 1%, 15 ml OP	Martindale Atropt	2024 2023
Azithromycin	Tab 500 mg	Zithromax	2024
Bacillus calmette-guerin vaccine	Inj Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated, vial with diluent	BCG Vaccine	2024
Baclofen	Inj 2 mg per ml, 5 ml ampoule	Medsurge	2024
Bendroflumethiazide [Bendrofluazide]	Tab 2.5 mg & 5 mg	Arrow- Bendrofluazide	2023
Benzatropine mesylate	Inj 1 mg per ml, 2 ml	Phebra	2023
Benzylpenicillin sodium [Penicillin G]	Inj 600 mg (1 million units) vial	Sandoz	2023
Betahistine dihydrochloride	Tab 16 mg	Serc	2023
Betamethasone dipropionate	Crm & oint 0.05%, 50 g OP	Diprosone	2023
Betamethasone dipropionate with calcipotriol	Oint 500 mcg with calcipotriol 50 mcg per g, 30 g OP Gel 500 mcg with calcipotriol 50 mcg per g, 60 g OP	Daivobet	2024

Generic Name	Presentation	Brand Name	Expiry Date*
Betamethasone valerate	Lotn 0.1%, 50 ml OP Oint 0.1%, 50 g OP Crm 0.1%, 50 g OP Scalp app 0.1%, 100 ml OP	Betnovate Beta Ointment Beta Cream Beta Scalp	2024
Bicalutamide	Tab 50 mg	Binarex	2023
Bimatoprost	Eye drops 0.03%, 3 ml OP	Bimatoprost Multichem	2024
Bisacodyl	Tab 5 mg Suppos 10 mg	Pharmacy Health Lax-suppositories	2024
Bisoprolol fumarate	Tab 2.5 mg, 5 mg & 10 mg	Bisoprolol Mylan	2023
Bosentan	Tab 62.5 mg & 125 mg	Bosentan Dr Reddy's	2024
Brimonidine tartrate	Eye drops 0.2%, 5 ml OP	Arrow-Brimonidine	2024
Brinzolamide	Eye drops 1%, 5 ml OP	Azopt	2024
Budesonide	Metered aqueous nasal spray, 50 mcg & 100 mcg per dose, 200 dose OP	SteroClear	2023
Bupropion hydrochloride	Tab modified-release 150 mg	Zyban	2023
Bezafibrate	Tab 200 mg Tab long-acting 400 mg	Bezalip Bezalip Retard	2024
Buspirone hydrochloride	Tab 5 mg & 10 mg	Buspirone Viatris	2024
Calamine	Crm, aqueous, BP, 100 g	Calamine-AFT	2024
Calcium carbonate	Tab 1.25 g (500 mg elemental)	Calci-Tab 500	2023
Candesartan cilexetil	Tab 4 mg, 8 mg,16 mg & 32 mg	Candestar	2024
Capsaicin	Crm 0.025%, 45 g OP Crm 0.075%, 45 g OP	Zostrix Zostrix HP	2023
Cefazolin	Inj 500 mg & 1 g vial	AFT	2023
Cetirizine hydrochloride	Oral liq 1 mg per ml, 200 ml	Hisatclear	2024
Cetomacrogol	Crm BP, 500 g	Cetomacrogol-AFT	2024
Cinacalcet	Tab 30 mg & 60 mg	Cinacalcet Devatis	2024
Ciprofloxacin	Eye drops 0.3%, 5 ml OP Tab 250 mg, 500 mg & 750 mg	Ciprofloxacin Teva Cipflox	2024 2023
Citalopram hydrobromide	Tab 20 mg	PSM Citalopram	2024
Clarithromycin	Tab 250 mg & 500 mg	Klacid	2024
Clomipramine hydrochloride	Tab 10 mg & 25 mg	Clomipramine Teva	2024
Clonidine	Patch 2.5 mg, 100 mcg per day Patch 5 mg, 200 mcg per day Patch 7.5 mg, 300 mcg per day	Mylan	2023
Clonidine hydrochloride	Inj 150 mcg per ml, 1 ml ampoule Tab 150 mcg	Medsurge Catapres	2024

Generic Name	Presentation	Brand Name	Expiry Date*
Codeine phosphate	Tab 15 mg, 30 mg & 60 mg	PSM	2023
Colecalciferol	Cap 1.25 mg (50,000 iu)	Vit.D3	2023
Condoms	60 mm 49 mm 53 mm, 0.05 mm thickness 53 mm 53 mm, strawberry, red 53 mm, chocolate, brown 56 mm	Shield XL Gold Knight Moments	30/09/2022
	56 mm, 0.08 mm thickness 56 mm, 0.08 mm thickness, red 56 mm, 0.05 mm thickness 56 mm, chocolate 56 mm, strawberry	Gold Knight	
Crotamiton	Crm 10%, 20 g OP	Itch-soothe	2024
Cyclizine hydrochloride	Tab 50 mg	Nausicalm	2024
Cyclophosphamide	Tab 50 mg	Cylconex	2024
Cyproterone acetate	Tab 50 mg & 100 mg	Siterone	2024
Cyproterone acetate with ethinyloestradiol	Tab 2 mg with ethinyloestradiol 35 mcg and 7 inert tabs	Ginet	2023
Darunavir	Tab 400 mg & 600 mg	Darunavir Mylan	2023
Desmopressin acetate	Nasal spray 10 mcg per dos, 6 ml OP	Desmopressin-PH&	Γ 2023
Dexamethasone	Tab 0.5 mg & 4 mg	Dexmethsone	2024
Dexamfetamine sulfate	Tab 5 mg	PSM	2024
Diazepam	Tab 2 mg & 5 mg	Arrow-Diazepam	2023
Diclofenac	Eye drops 0.1%, 5 ml OP	Voltaren Ophtha	2024
Diclofenac sodium	Tab EC 25 mg & 50 mg	Diclofenac Sandoz	2024
Diltiazem hydrochloride	Cap long-acting 180 mg & 240 mg	Cardizem CD	2024
Diphtheria, tetanus and pertussis vaccine	Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg pertussis toxoid, 8 mcg pertussis filamentous haemagglutinin and 2.5 mcg pertactin in 0.5 ml syringe	Boostrix	2024
Diphtheria, tetanus, pertussis and polio vaccine	Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin and 80 D-antigen units poliomyelitis virus in 0.5ml syringe	Infanrix IPV	2024

Generic Name	Presentation	Brand Name	Expiry Date*
Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type B vaccine	Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin, 80 D-AgU polio virus, 10 mcg hepatitis B surface antigen in 0.5ml syringe	Infanrix-hexa	2024
Disulfiram	Tab 200 mg	Antabuse	2024
Docusate sodium	Tab 50 mg & 120 mg	Coloxyl	2023
Domperidone	Tab 10 mg	Pharmacy Health	2024
Donepezil hydrochloride	Tab 5 mg & 10 mg	Donepezil-Rex	2023
Dorzolamide with timolol	Eye drops 2% with timolol 0.5%, 5 ml OP	Dortimopt	2024
Emulsifying ointment	Oint BP	Emulsifying Ointmen ADE	t 2023
Entacapone	Tab 200 mg	Comtan	2024
Eplerenone	Tab 25 mg & 50 mg	Inspra	2024
Escitalopram	Tab 10 mg & 20 mg	Escitalopram (Ethics)	2024
Etanercept	Inj 25 mg Inj 50 mg autoinjector Inj 50 mg prefilled syringe	Enbrel	2024
Ezetimibe	Tab 10 mg	Ezetimibe Sandoz	2023
Febuxostat	Tab 80 mg & 120 mg	Febuxostat multichem	2023
Felodipine	Tab long-acting 5 mg Tab long-acting 10 mg	Felo 5 ER Felo 10 ER	2024
Fentanyl	Inj 50 mcg per ml, 2ml ampoule	Boucher and Muir	2024
	Inj 50 mcg per ml, 10 ml ampoule Patch 12.5 mcg per hour Patch 25 mcg per hour Patch 50 mcg per hour Patch 75 mcg per hour Patch 100 mcg per hour	Fentanyl Sandoz	
Ferrous fumarate	Tab 200 mg (65 mg elemental)	Ferro-tab	2024
Filgrastim	lnj 300 mcg per 0.5 ml & 480 mcg per 0.5 ml	Nivestim	2024
Finasteride	Tab 5 mg	Ricit	2023
Flucloxacillin	Cap 250 mg & 500 mg Grans for oral liq 25 mg per ml Grans for oral liq 50 mg per ml	Flucloxacillin-AFT AFT	2024
	Inj 1 g vial	Flucil	2023
Fluconazole	Cap 50 mg, 150 mg & 200 mg	Mylan	2023

Generic Name	Presentation	Brand Name	Expiry Date*
Fluorouracil sodium	Crm 5%, 20 g OP	Efudix	2024
Fluticasone	Aerosol inhaler 50 mcg, 125 mcg & 250 mcg per dose, 120 dose OP	Flixotide	2023
Fluticasone propionate	Metered aqueous nasal spray, 50 mcg per dose, 120 dose OP	Flixonase Hayfever & Allergy	& 2024
Fluticasone with salmeterol	Aerosol inhaler 50 mcg with salmeterol 25 mcg & 125 mcg with salmeterol 25 mcg, 120 dose OP	Seretide	2023
Folic acid	Tab 5 mg	Folic Acid Mylan	2024
Furosemide [frusemide]	Tab 40 mg	IPCA-Frusemide	2024
Gabapentin	Cap 100 mg, 300 mg & 400 mg	Nupentin	2024
Glibenclamide	Tab 5 mg	Daonil	2024
Gliclazide	Tab 80 mg	Glizide	2023
Glipizide	Tab 5 mg	Minidiab	2024
Glucagon hydrochloride	Inj 1 mg syringe kit	Glucagen Hypokit	2023
Glucose [Dextrose]	Inj 50%, 10 ml ampoule Inj 50%, 90 ml bottle	Biomed	2023
Glycerol	Liquid	healthE Glycerol BP	2023
Glyceryl trinitrate	Oint 0.2%, 30 g OP	Rectogesic	2024
Goserelin	Implant 3.6 mg & 10.8 mg, syringe	Teva	2023
Hepatitis A vaccine	Inj 1440 ELISA units in 1 ml syringe Inj 720 ELISA units in 0.5 ml syringe	Havrix Havrix Junior	2024
Hepatitis B recombinant vaccine	Inj 20 mcg per 1 ml prefilled syringe	Engerix-B	2024
Human papillomavirus (6, 11, 16, 18, 31, 33, 45, 52 and 58) vaccine [HPV]	Inj 270 mg in 0.5 ml syringe	Gardasil 9	2024
Hydrocortisone	Inj 100 mg vial	Solu-Cortef	2024
Hydrocortisone and paraffin liquid and lanolin	Lotn 1% with paraffin liquid 15.9% and lanolin 0.6%	DP Lotn HC	2023
Hydrocortisone butyrate	Oint 0.1%, 100 g OP Scalp lotn 0.1%, 100 ml OP	Locoid	2024
The description of the	Milky emuls 0.1%, 100 ml 0P	Locoid Crelo	0004
Hydrocortisone with miconazole	Crm 1% with miconazole 2%, 15 g OP	Micreme H	2024
Hydroxyurea [hydroxycarbamide]	Cap 500 mg	Devatis	2023
Hyoscine butylbromide	Tab 10 mg Inj 20 mg, 1 ml	Buscopan	2023

Generic Name	Presentation	Brand Name	Expiry Date*
Ibuprofen	Oral liq 20 mg per ml, 200 ml Tab long-acting 800 mg Tab 200 mg	Ethics Brufen SR Relieve	2024
Imatinib mesylate	Cap 100 mg & 400 mg	Imatinib-Rex	2023
Indapamide	Tab 2.5 mg	Dapa-Tabs	2023
Ipratropium bromide	Aqueous nasal spray, 0.03%, 15 ml OP	Univent	2023
Isoniazid	Tab 100 mg	PSM	2024
Isoniazid with rifampicin	Tab 100 mg with rifampicin 150 mg Tab 150 mg with rifampicin 300 mg	Rifinah	2024
Isosorbide mononitrate	Tab 20 mg Tab long-acting 40 mg Tab long-acting 60 mg	ISMO 20 ISMO 40 Retard Duride	2023
Isotretinoin	Cap 5 mg, 10 mg & 20 mg	Oratane	2024
Ispaghula (psyllium) husk	Powder for oral soln, 500 g OP	Konsyl-D	2023
Ketoconazole	Shampoo 2%, 100 ml OP	Sebizole	2023
Labetalol	Tab 100 mg & 200 mg	Trandate	2024
Lamivudine	Tab 100 mg Tab 150 mg	Zetlam Lamivudine Alphapharm	2023
Lansoprazole	Cap 15 mg & 30 mg	Lanzol Relief	2024
Latanoprost	Eye drop 0.005%, 2.5 ml OP	Teva	2024
Latanoprost with timolol	Eye drops 0.005% with timolol 0.5%, 2.5 ml OP	Arrow - Lattim	2023
Leflunomide	Tab 10 mg & 20 mg	Arava	2023
Letrozole	Tab 2.5 mg	Letrole	2024
Levodopa with carbidopa	Tab long-acting 200 mg with carbidopa 50 mg Tab 100 mg with carbidopa 25 mg & 250 mg with carbidopa 25 mg	Sinemet CR Sinemet	2023
Levonorgestrel	Subdermal implant (2 x 75 mg rods) Intra-uterine device system 52 mg Intra-uterine device system 13.5 mg	Jadelle Mirena Jaydess	2023 31/10/2022
Lithium carbonate	Tab long-acting 400 mg	Priadel	2024
Lopinavir with ritonavir	Tab 100 mg with ritonavir 25 mg Tab 200 mg with ritonavir 50 mg	Lopinavir/Ritonavir Mylan	2024
Lorazepam	Tab 1 mg & 2.5 mg	Ativan	2024
Losartan potassium	Tab 12.5 mg, 25 mg, 50 mg & 100 mg	Losartan Actavis	2023

Generic Name	Presentation	Brand Name	Expiry Date*
Macrogol 3350 with potassium chloride, sodium bicarbonate and sodium chloride	Powder for oral soln 13.125 g with potassium chloride 46.6 mg, sodium bicarbonate 178.5 mg and sodium chloride 350.7 mg	Molaxole	2023
Magnesium sulphate	Inj 2 mmol per ml, 5 ml ampoule	Martindale	2023
Measles, mumps and rubella vaccine	Inj, measles virus 1,000 CCID50, mumps virus 5,012 CCID50, Rubella virus 1,000 CCID50; prefilled syringe/ampoule of diluent 0.5 ml	Priorix	2024
Mebendazole	Tab 100 mg	Vermox	2024
Mebeverine hydrochloride	Tab 135 mg	Colofac	2023
Melatonin	Tab modified-release 2 mg	Vigisom	2024
Meningococcal (groups A, C, Y and W-135) conjugate vaccine	Inj 4 mcg of each meningococcal polysaccharide conjugated to a total of approximately 48 mcg of diphtheria toxoid carrier per 0.5 ml vial	Menactra	2024
Mesalazine	Tab long-acting 500 mg	Pentasa	2023
Methadone	Oral liq 2 mg per ml Oral liq 5 mg per ml Oral liq 10 mg per ml	Biodone Biodone Forte Biodone Extra Forte	2024
Methotrexate	Tab 2.5 mg & 10 mg Inj 100 mg per ml, 50 ml vial	Trexate Methotrexate Ebewe	2024 2023
Methylprednisolone aceponate	Crm & oint 0.1%, 15 g OP	Advantan	2023
Metoclopramide hydrochloride	Tab 10 mg	Metoclopramide Actavis 10	2023
Metoprolol tartrate	Tab 50 mg & 100 mg	IPCA-Metoprolol	2024
Metronidazole	Tab 200 mg & 400 mg	Metrogyl	2023
Metyrapone	Cap 250 mg	Metopirone	2023
Miconazole	Oral gel 20 mg per g, 40 g OP	Decozol	2024
Miconazole nitrate	Crm 2%, 15 g OP Vaginal crm 2% with applicator, 40 g OP	Multichem Micreme	2023
Mirtazapine	Tab 30 mg & 45 mg	Noumed	2024
Moclobemide	Tab 150 mg & 300 mg	Aurorix	2024
Modafinil	Tab 100 mg	Modavigil	2024
Mometasone furoate	Crm 0.1%, 15 g OP Crm 0.1%, 50 g OP Oint 0.1%, 15 g OP Oint 0.1%, 50 g OP Lotn 0.1%, 30 ml OP	Elocon Alcohol Free	2024

Generic Name	Presentation	Brand Name	Expiry Date*
Morphine sulphate	Tab immediate-release 10 mg & 20 mg	Sevredol	2023
Moxifloxacin	Tab 400 mg	Avelox	2023
Nadolol	Tab 40 mg & 80 mg	Nadolol BNM	2024
Naltrexone hydrochloride	Tab 50 mg	Naltraccord	2023
Naproxen	Tab 250 mg Tab 500 mg Tab long-acting 750 mg Tab long-acting 1 g	Noflam 250 Noflam 500 Naprosyn SR 750 Naprosyn SR 1000	2024
Neostigmine metilsulfate	Inj 2.5 mg per ml, 1 ml ampoule	Max Health	2024
Nevirapine	Tab 200 mg	Nevirapine Alphapharm	2024
Nitrofurantoin	Cap modified-release 100 mg	Macrobid	2023
Norethisterone	Tab 350 mcg	Noriday 28	2024
Nystatin	Oral liq 100,000 u per ml, 24 ml OP Vaginal crm 100,000 u per 5 g with applicator(s), 75 g OP	Nilstat	2023
Octreotide	Inj 50 mcg per ml, 1 ml ampoule Inj 100 mcg per ml, 1 ml ampoule Inj 500 mcg per ml, 1 ml ampoule	Max Health	2024
Octreotide long-acting	Inj depot 10 mg, 20 mg & 30 mg prefilled syringe	Octreotide Depot Teva	2024
Oestriol	Crm 1 mg per g with applicator, 15 g OP Pessaries 500 mcg Tab 2 mg	Ovestin Ovestin	2023
Olanzapine	Orodispersible tab 5 mg & 10 mg Tab 2.5 mg, 5 mg and 10 mg	Zypine ODT Zypine	2023
Omeprazole	Cap 10 mg	Omeprazole actavis	2023
	Cap 20 mg	10 Omeprazole actavis 20	
	Cap 40 mg	Omeprazole actavis 40	
Ondansetron	Tab disp 4 mg & 8 mg	Ondansetron ODT- DRLA	2023
Ornidazole	Tab 500 mg	Arrow-Ornidazole	2024
Orphenadrine citrate	Tab 100 mg	Norflex	2024

Generic Name	Presentation	Brand Name	Expiry Date*
Oxycodone hydrochloride	Inj 10 mg per ml, 1 ml and 2 ml ampoule Inj 50 mg per ml, 1 ml ampoule	Hameln	2024
	Tab controlled-release 5 mg, 10 mg, 20 mg, 40 mg & 80 mg	Oxycodone Sandoz	
	Cap immediate-release 5 mg, 10 mg & 20 mg Oral liq 5 mg per 5 ml	OxyNorm	
Pancreatic enzyme	Cap prancreatin 150 mg (amylase 8,000 Ph Eur U lipase 10,000 Ph Eur U, total protease 600 Ph Eur U) Cap prancreatin 300 mg (amylase 18,000 Ph Eur U lipase 25,000 Ph Eur U, total protease 1,000 Ph Eur U)	Creon 10000 Creon 25000	2024
Paracetamol	Tab 500 mg-bottle pack Tab 500 mg-blister pack	Noumed Paracetamo	2024
	Oral liq 120 mg per 5 ml Oral liq 250 mg per 5 ml	Paracare Paracare Double Strength	2023
Perindopril	Tab 2 mg & 4 mg	Coversyl	2024
Permethrin	Crm 5%, 30 g OP Lotn 5%, 30 ml OP	Lyderm A-Scabies	2023
Pethidine hydrochloride	Tab 50 mg	PSM	2024
Phenoxymethylpenicillin (penicillin V)	Cap 250 mg Cap 500 mg	Cilicaine VK	2024
Pimecrolimus	Crm 1%, 15 g OP	Elidel	2023
Pine tar with trolamine laurisulfate and fluorescein	Soln 2.3% with trolamine laurilsulfate and fluorescein sodium	Pinetarsol	2023
Pioglitazone	Tab 15 mg, 30 mg & 45 mg	Vexazone	2024
Pneumococcal (PCV10) conjugate vaccine	Inj 1 mcg of pneumococcal polysaccharide serotypes 1, 5, 6B, 7F, 9V, 14 and 23F; 3 mcg of pneumococcal polysaccharide serotypes 4, 18C and 19F in 0.5 ml prefilled syringe	Synflorix	2024
Pneumococcal (PPV23) polysaccharide vaccine	Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype)	Pneumovax 23	2024
Poliomyelitis vaccine	Inj 80D antigen units in 0.5 ml syringe	IP0L	2024
Poloxamer	Oral drops 10%, 30 ml OP	Coloxyl	2023
Potassium iodate	Tab 253 mcg (150 mcg elemental iodine)	NeuroTabs	2023
Povidone iodine	Antiseptic solution 10%, 100 ml Oint 10%, 65 g OP	Riodone Betadine	2024 2023
Pravastatin	Tab 20 mg & 40 mg	Pravastatin Mylan	2023

Generic Name	Presentation	Brand Name	Expiry Date*
Prednisolone	Oral liq 5 mg per ml, 30 ml OP	Redipred	2024
Prochlorperazine	Tab 5 mg	Nausafix	2023
Propranolol	Tab 10 mg Tab 40 mg	Drofate IPCA-Propranolol	2024
Pyridoxine hydrochloride	Tab 25 mg	Vitamin B6 25	2023
Quetiapine	Tab 25 mg, 100 mg, 200 mg & 300 mg	Quetapel	2023
Quinapril	Tab 5 mg Tab 10 mg Tab 20 mg	Arrow-Quinapril 5 Arrow Quinapril 10 Arrow-Quinapril 20	2024
Quinapril with	Tab 10 mg with hydrochlorothiazide	Accuretic 10	2024
hydrochlorothiazide	12.5 mg Tab 20 mg with hydrochlorothiazide 12.5 mg	Accuretic 20	
Rifampicin	Cap 150 mg & 300 mg Oral liq 100 mg per 5 ml	Rifadin	2023
Rifaximin	Tab 550 mg	Xifaxan	2023
Riluzole	Tab 50 mg	Rilutek	2024
Risperidone	Tab 0.5 mg, 1 mg, 2 mg, 3 mg & 4 mg Oral liq 1 mg per ml	Risperidone (Teva) Risperon	2023
Rituximab	Inj 100 mg per 10 ml vial & 500 mg per 50 ml vial	Riximyo	30/09/2023
Rivastigmine	Patch 4.6 mg per 24 hour	Rivastigmine Patch	2024
	Patch 9.5 mg per 24 hour	BNM 5 Rivastigmine Patch BNM 10	
Rizatriptan	Tab orodispersible 10 mg	Rizamelt	2023
Rosuvastatin	Tab 5 mg, 10 mg, 20 mg and 40 mg	Rosuvstatin Viatris	2023
Rotavirus oral vaccine	Oral susp live attenuated human rotavirus 1,000,000 CCID50 per dose, prefilled oral applicator	Rotarix	2024
Salbutamol	Oral liq 400 mcg per ml, 150 ml Nebuliser soln 1 mg per ml, 2.5 ml ampoule Nebuliser soln 2 mg per ml, 2.5 ml ampoule	Ventolin Asthalin	2024
Salbutamol with ipratropium bromide	Nebuliser soln, 2.5 mg with ipratropium bromide 0.5 mg per vial, 2.5 ml ampoule	Duolin	2024
Sildenafil	Tab 25 mg, 50 mg & 100 mg	Vedafil	2024
Simvastatin	Tab 10 mg, 20 mg, 40 mg & 80 mg	Simvastatin Mylan	2023
Sodium citro-tartrate	Grans eff 4 g sachets	Ural	2023
Sodium fusidate [Fusidic acid]	Crm 2%, 5 g OP Oint 2%, 5 g OP	Foban	2024

^{*}Expiry date of the SSS/PSS period is 30 June of the year indicated unless otherwise stated. Please note that SSS/PSS may have been awarded for a wider scope than just those presentation(s) listed in the above table.

Generic Name	Presentation	Brand Name	Expiry Date*
Sodium hyaluronate [hyaluronic acid]	Eye drops 1 mg per ml, 10 ml OP	Hylo-Fresh	2024
Solifenacin succinate	Tab 5 mg & 10 mg	Solifenacin Mylan	2024
Somatropin (Omnitrope)	Inj 5 mg, 10 mg & 15 mg cartridge	Omnitrope	2024
Sumatriptan	Tab 50 mg & 100 mg	Sumagran	2024
Sunitinib	Cap 12.5 mg, 25 mg & 50 mg	Sunitinib Pfizer	2024
Tacrolimus	Oint 0.1%, 30 g OP	Zematop	2023
Taliglucerase alfa	Inj 200 unit vial	Elelyso	2023
Tamoxifen citrate	Tab 10 mg & 20 mg	Tamoxifen Sandoz	2023
Temazepam	Tab 10 mg	Normison	2023
Terbinafine	Tab 250 mg	Deolate	2023
Teriflunomide	Tab 14 mg	Aubagio	2023
Timolol	Eye drops 0.25% & 0.5%, 5 ml OP	Arrow-Timolol	2023
Tobramycin	Inj 40 mg per ml, 2 ml vial Solution for inhalation 60 mg per ml, 5 ml	Tobramycin Mylan Tobramycin BNM	2024 2023
Tramadol hydrochloride	Cap 50 mg Tab sustained-release 100 mg Tab sustained-release 150 mg Tab sustained-release 200 mg	Arrow-Tramadol Tramal SR 100 Tramal SR 150 Tramal SR 200	2023
Travoprost	Eye drops 0.004%, 2.5 ml OP	Travatan	2024
Tretinoin	Crm 0.5 mg per g, 50 g OP	ReTrieve	2024
Triamcinolone acetonide	Inj 10 mg per ml, 1 ml ampoule Inj 40 mg per ml, 1 ml ampoule Paste 0.1%, 5 g OP Crm & oint 0.02%, 100 g OP	Kenacort-A 10 Kenacort-A 40 Kenalog in Orabase Aristocort	2023
Trimethoprim	Tab 300 mg	TMP	2024
Trimethoprim with sulphamethoxazole [co-trimoxazole]	Tab trimethoprim 80 mg and sulphamethoxazole 400 mg	Trisul	2024
Tuberculin PPD [Mantoux] test	Inj 5 TU per 0.1 ml, 1 ml vial	Tubersol	2024
Ursodeoxycholic acid	Cap 250 mg	Ursosan	2023
Valaciclovir	Tab 500 mg & 1,000 mg	Valclovir	2024
Valganciclovir	Tab 450 mg	Valganciclovir Mylar	n 2024
Vancomycin	Inj 500 mg vial	Mylan	2023
Varenicline tartrate	Tab 0.5 mg x 11 and 1 mg x 42, 53 OP Tab 1 mg	Varenicline Pfizer	2024
Varicella vaccine [Chickenpox vaccine]	Inj 1350 PFU prefilled syringe	Varivax	2024

Generic Name	Presentation	Brand Name I	Expiry Date*
Zoledronic acid	Inj 4 mg per 5 ml, vial	Zoledronic Acid Mylan	2024
Zopiclone	Tab 7.5 mg	Zopiclone Actavis	2024

July 2022 changes are in bold type

	ck your Schedule for full details edule page ref	Subsidy (Mnfr's price) \$	Per	Brand or Generic Mnfr fully subsidised
Ne	w Listings			
	ctive 1 July 2022			
100	TENOFOVIR DISOPROXIL Tenofovir disoproxil prescribed under endorser subsidised antiretrovirals for the purposes of S * Tab 245 mg (300.6 mg as a maleate)	pecial Authority SA2139.	/ is inclu 30	uded in the count of up to 4 Tenofovir Disoproxil Mylan
102	EMTRICITABINE WITH TENOFOVIR DISOPROXIL - see SA2138 Endorsement for treatment of HIV: Prescription disoproxil is co-prescribed with another antiret prescription is annotated accordingly by the Ph Note: Emtricitabine with tenofovir disoproxil pre included in the count of up to 4 subsidised anti the purposes of Special Authority SA2139. The prescribe antiretroviral therapy in New Zealand. Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a maleate)	is deemed to be endorsed proving subsidised under Spearmacist or endorsed by the escribed under endorsemen iretrovirals, and counts as twee is an approval process to Further information is avail	if emtric ecial Aut e prescr t for the vo antire o becom	itabine with tenofovir thority SA2139 and the iber. treatment of HIV is etroviral medications, for the a named specialist to
130	METOCLOPRAMIDE HYDROCHLORIDE * Inj 5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	7.00	10	∠ Baxter
175	GEMTUZUMAB OZOGAMICIN – PCT only – Specia Inj 5 mg vial	r this condition; and bid leukaemia; and caemia; and ination with standard anthration with standard and intensive remission induct course only; and red as one dose at 3 mg per to be administered romyelocytic leukaemia and myelodysplasia or myelopri	1 or application a	eations meeting the and cytarabine (AraC); and rmediate; and motherapy with by surface area; or myeloid leukaemia that is
183	ADALIMUMAB (HUMIRA) – Special Authority see Inj 20 mg per 0.2 ml prefilled syringe		2	✓ Humira
241	ACETYLCYSTEINE			

Note – this is a new Pharmacode listing 2634864.

Inj 200 mg per ml, 10 ml ampoule52.88

10

✓ Martindale Pharma

[▲] Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist

Changes to Restrictions, Chemical Names and Presentations Effective 1 July 2022

25	DOCUSATE SODIUM WITH SENNOSIDES (stat dispensing removed) Tab 50 mg with sennosides 8 mg	200	∠ Laxsol
31	TALIGLUCERASE ALFA – Special Authority see SA2137 1880 – Retail pharm criteria and moving from panel to Special Authority) Inj 200 unit vial	acy (amer	nded Special Authority ✓ Elelyso
	Special Authority for Subsidy Special Authority approved by the Gaucher Treatment Panel		
	Notes: Application details may be obtained from Pharmac's website scheduk The Co-ordinator, Gaucher Treatment Panel Phone: 6).pharmac)4 460 49!	•
	,	e: 04 916	
	- Wellington Email: ga	aucherpan	el@pharmac.govt.nz
	Completed application forms must be sent to the coordinator for the Gaucher	Treatmen	t Panel and will be
	considered by the Gaucher Treatment Panel at the next practicable opportunit	y. Notifica	tion of the Gaucher
	Treatment Panel's decision will be sent to the patient, the applying clinician a	nd the pati	ient's GP (if specified).

Access Criteria

Initial application from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1) The patient has a diagnosis of symptomatic type 1 or type 3* Gaucher disease confirmed by the demonstration of specific deficiency of alucocerebrosidase in leukocytes or cultured skin fibroblasts, and genotypic analysis: and
- 2) Patient does not have another life-threatening or severe disease where the prognosis is unlikely to be influenced by taliglucerase alfa or might be reasonably expected to compromise a response to therapy with taliglucerase alfa: and
- 3) 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), unless otherwise agreed by Pharmac; and
- 4) Supporting clinical information including test reports, MRI whole body STIR, haematological data, and other relevant investigations, are submitted to the Gaucher Panel for assessment; and
- 5) Any of the following:
 - 1) Patient has haematological complications such as haemoglobin less than 95 g/l, symptomatic anaemia, thrombocytopenia; at least two episodes of severely symptomatic splenic infarcts confirmed with imagery; or massive symptomatic splenomegaly: or
 - 2) Patient has skeletal complications such as acute bone crisis requiring hospitalisation or major pain management strategies: radiological MRI Evidence of incipient destruction of any major joint (e.g. hipsor shoulder); spontaneous fractures or vertebral collapse; chronic bone pain not controlled by other pharmaceuticals: or
 - 3) Patient has significant liver dysfunction or hepatomegaly attributable to Gaucher disease; or
 - 4) Patient has reduced vital capacity from clinically significant or progressive pulmonary disease due to Gaucher disease: or
 - 5) Patient is a child and has experienced growth failure with significant decrease in percentile linear growthover a 6-12 month period.

*Unapproved indication

Renewal from any relevant practitioner. Approvals valid for 12 months for applications meeting the followingcriteria:

1) Patient has demonstrated a symptomatic improvement or no deterioration in the main symptom for whichtherapy was initiated: and

Check your Schedule for full details	Subsidy	Brand or
Schedule page ref	(Mnfr's price)	Generic Mnfr
	\$ Per	✓ fully subsidised

continued...

- Patient has demonstrated a clinically objective improvement or no deterioration in haemoglobin levels, plateletcounts and liver and spleen size: and
- 3) Radiological (MRI) signs of bone activity performed at two years since initiation of treatment, and three yearly thereafter, demonstrate no deterioration shown by the MRI, compared with MRI taken immediately prior tocommencement of therapy or adjusted dose; and
- 4) Patient has not had severe infusion-related adverse reactions which were not preventable by appropriate premedication and/or adjustment of infusion rates; and
- 5) Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT; and
- 6) Patient is compliant with regular treatment and taliglucerase alfa is to be administered at a dose no greaterthan 30 unit/kg every other week rounded to the nearest whole vial (200 units), unless otherwise agreed by Pharmac: and
- 7) Supporting clinical information including test reports, MRI whole body STIR, haematological data, and other relevant investigations are submitted to the Gaucher Panel for assessment as required.

Initial application – only from a metabolic physician. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 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
- 2 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
- 3 Any of the following:
 - 3.1 Patient has haematological complications of Gaucher disease: or
 - 3.2 Patient has skeletal complications of Gaucher disease; or
 - 3.3 Patient has significant liver dysfunction or hepatomegaly attributable to Gaucher disease; or
 - 3.4 Patient has reduced vital capacity from clinically significant or progressive pulmonary disease due to Gaucher disease: or
 - 3.5 Patient is a child and has experienced growth failure with significant decrease in percentile linear growth over a 6-12 month period; and
- 4 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 – from a metabolic physician or any relevant practitioner on the recommendation of a metabolic physician. Approvals valid for 3 years for applications meeting the following criteria:

- All of the following:
- 1 Patient has demonstrated a symptomatic improvement and has maintained improvements in the main symptom or symptoms for which therapy was started; and
- 2 Patient has demonstrated a clinically objective improvement or no deterioration in haemoglobin levels, platelet counts and liver and spleen size; and
- 3 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
- 4 Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT: and
- 5 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).

62	OXYTOCIN WITH ERGOMETRINE MALEATE – up to 5 inj availab Inj 5 iu with ergometrine maleate 500 mcg per ml,	ie on a PSO (a	mended	presentation description)
	1 ml ampoule	32.40	5	✓ Syntometrine
78	CINACALCET – Special Authority see SA1618 – Retail pharmacy Tab 30 mga) Brand switch fee payable (Pharmacode 2634120) b) Wastage claimable		h fee rem 28	noved) <u>Cinacalet Devatis</u>
102	EMTRICITABINE WITH TENOFOVIR DISOPROXIL — Subsidy by e see SA2138 1994 (amended Special Authority criteria and addit Endorsement for treatment of HIV: Prescription is deemed to disoproxil is co-prescribed with another antiretroviral subsidis prescription is annotated accordingly by the Pharmacist or er Note: Emtricitabine with tenofovir disoproxil prescribed under included in the count of up to 4 subsidised antiretrovirals, and the purposes of Special Authority SA2139. There is an approprescribe antiretroviral therapy in New Zealand. Further inform Tab 200 mg with tenofovir disoproxil 245 mg	ion of stat disp be endorsed if sed under Spen ndorsed by the endorsement d counts as twall val process to nation is availa	pensing) femtricita cial Author prescrib for the tro o antiretr become ble on the	abine with tenofovir ority SA2139 and the er. eatment of HIV is roviral medications, for a named specialist to e Pharmac website.
	(300.6 mg as a succinate)* * Tab 200 mg with tenofovir disoproxil 245 mg	61.15	30	✓ Teva
	(300.6 mg as a maleate)	15.45	30	✓ Tenofovir Disoproxil

➤ SA2138 1994 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 3 24 months for applications meeting the following criteria:

All of the following Both:

- 1 Applicant has an up to date knowledge of the safety issues and is competent to prescribe pre-exposureprophylaxis (refer to local health pathways or https://ashm.org.au/HIV/PrEP/ for training materials); and
- Patient has undergone testing for HIV, syphilis and Hep B if not immune and a full STI screen in the previoustwo weeks: and
- 3 Patient has had renal function testing (creatinine, phosphate and urine protein/creatinine ratio) within the last 3 months and is not contraindicated for treatment; and
- 4 Patient has received advice regarding the reduction of risk of HIV and sexually transmitted infections and howto reduce those risks; and
- 51 Patient has tested HIV negative and is not at risk of HIV seroconversion, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion; and
- 6 Either:
 - 6.1 All of the following:
 - 6.1.1 Patient is male or transgender: and
 - 6.1.2 Patient has sex with men; and
 - 6.1.3 Patient is likely to have multiple episodes of condomless anal intercourse in the next 3 months;
 - 6.1.4 Any of the following:
 - 6.1.4.1 Patient has had at least one episode of condomless receptive anal intercourse with one or more casual male partners in the last 3 months; or
 - 6.1.4.2 A diagnosis of rectal chlamydia, rectal gonorrhoea, or infectious syphilis within the last 3 months; or
 - 6.1.4.3 Patient has used methamphetamine in the last three months; or

continued

Emtricitabine Mylan

Check your Schedule for full details	Subsidy	Brand or
Schedule page ref	(Mnfr's price)	Generic Mnfr
	\$ Per	✓ fully subsidised

continued...

- 6.2 All of the following:
 - 6.2.1 Patient has a regular partner who has HIV infection; and
 - 6.2.2 Partner is either not on treatment or has a detectable viral load; and
 - 6.2.3 Condoms have not been consistently used
- 2 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 from any relevant practitioner. Approvals valid for 3 24 months for applications meeting the following criteria:

All of the following Both:

- 4 Applicant has an up to date knowledge of the safety issues and is competent to prescribe pre-exposureprophylaxis (refer to local health pathways or https://ashm.org.au/HIV/PrEP/ for training materials); and
- 2 Patient has undergone testing for HIV, syphilis and Hep B if not immune and a full STI screen in the previous two weeks: and
- 3 Patient has had renal function testing (creatinine, phosphate and urine protein/creatinine ratio) within the last 12 months and is not contraindicated for treatment; and
- 4 Patient has received advice regarding the reduction of risk of HIV and sexually transmitted infections and howto reduce those risks: and
- 51 Patient has tested HIV negative and is not at risk of HIV seroconversion, does not have signs or symptoms of acute HIV infection and has been assessed for HIV seroconversion; and
- 6 Either:
 - 6.1 All of the following:
 - 6.1.1 Patient is male or transgender; and
 - 6.1.2 Patient has sex with men; and
 - 6.1.3 Patient is likely to have multiple episodes of condomless anal intercourse in the next 3 months; and
 - 6.1.4 Any of the following:
 - 6.1.4.1 Patient has had at least one episode of condomless receptive anal intercourse with one or more casual male partners in the last 3 months: or
 - 6.1.4.2 A diagnosis of rectal chlamydia, rectal gonorrhoea, or infectious syphilis within the last-3-months: or
 - 6.1.4.3 Patient has used methamphetamine in the last three months; or
 - 6.2 All of the following:
 - 6.2.1 Patient has a regular partner who has HIV infection; and
 - 6.2.2 Partner is either not on treatment or has a detectable viral load: and
 - 6.2.3 Condoms have not been consistently used.
- 2 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/)

104 Antiretrovirals (amended Special Authority criteria – affected criteria shown only)

► SA2139 1651 Special Authority for Subsidy

Initial application — (post-exposure prophylaxis following non-occupational exposure to HIV) only from a namedspecialist any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria: Both:

- 1 Treatment course to be initiated within 72 hours post exposure; and
- 2 Any of the following:
 - 2.1 Patient has had condomless unprotected receptive 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
 - 2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
 - 2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required; or
 - 2.4 Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown.

Notes: 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 quidelines for PEP (http://www.ashm.org.au/hiv/hiv-management/pep/)

Renewal – (second or subsequent post-exposure prophylaxis) only from a named specialist any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:

Both:

- 1 Treatment course to be initiated within 72 hours post exposure; and
- 2 Any of the following:
 - 2.1 Patient has had condomless unprotected receptive 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
 - 2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
 - 2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required; or
 - 2.4 Patient has had condomless anal intercourse with a person from a high HIV prevalence country or risk group whose HIV status is unknown.

105	Oral suspension 10 mg per ml	,	✓ Viramune Suspension
109	NITROFURANTOIN (addition of PSO and wastage claimable removed) ** Cap modified-release 100 mg - Up to 15 cap available on a PSO	100	✓ <u>Macrobid</u>
118	ENTACAPONE – Brand switch fee payable (Pharmacode 2634139) (brand ▲ Tab 200 mg18.04	switch fee re	emoved) ✓ <u>Comtan</u>
130	CYCLIZINE LACTATE (amended presentation description) Inj 50 mg per ml, 1 ml ampoule 16.36	10	✓ Hameln

Check your Schedule for full details	Subsidy	Brand or
Schedule page ref	(Mnfr's price)	Generic Mnfr
	\$ Per	✓ fully subsidised

134 Multiple Sclerosis Treatments (amended Special Authority criteria)

➤ SA2140 2051 Special Authority for Subsidy

Initial application – (Multiple sclerosis) Applications only from a neurologist or general physician. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Diagnosis of multiple sclerosis (MS) meets the McDonald 2017 diagnostic criteria for MS and has been be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- 2 Patients must have Clinically Definite Relapsing multiple sclerosis with or without underlying progression; and
- 2 Patient must have has an EDSS score 0 6.0; and
- 3 Patient has had at least one significant attack relapse of MS in the previous 12 months or two significant attacks relapses in the past 24 months; and
- 4 All of the following:
 - 4.1 Each significant attack relapse must be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the attack relapse, but the neurologist/ physician must be satisfied that the clinical features were characteristic); and
 - 4.2 Each significant attack relapse is associated with characteristic symptom(s)/sign(s) or substantially worsening of previously experienced symptoms(s)/sign(s); and
 - 4.3 Each significant attack relapse has lasted at least one week and has started at least one month after the onset of a previous attack (where relevant); and
 - 4.4 Each significant attack relapse can be distinguished from the effects of general fatigue; and is not associated with a fever (T> 37.5°C); and
 - 4.5 Either:
 - 4.5.1 Each significant attack relapse is severe enough to change either the EDSS or at least one of the Kurtze Functional System scores by at least 1 point; or
 - 4.5.2 Each significant attack relapse is a recurrent paroxysmal symptom of multiple sclerosis (tonic seizures/spasms, trigeminal neuralgia, Lhermitte's symptom); and
- 5 Evidence of new inflammatory activity on an MRI scan within the past 24 months; and
- 6 Any of the following:
 - 6.1 A sign of that new inflammatory activity on MRI scanning (in criterion 5 immediately above) is a gadolinium enhancing lesion: or
 - 6.2 A sign of that new inflammatory activity is a lesion showing diffusion restriction; or
 - 6.3 A sign of that new inflammatory is a T2 lesion with associated local swelling; or
 - 6.4 A sign of that new inflammatory activity is a prominent T2 lesion that clearly is responsible for the clinical features of a recent attack relapse that occurred within the last 2 years; or
- 6.5 A sign of that new inflammatory activity is new T2 lesions compared with a previous MRI scan. Note: Natalizumab can only be dispensed from a pharmacy registered in the Tysabri Australasian Prescribing Programme operated by the supplier. Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

Renewal – (Multiple sclerosis) only from a neurologist or general physician. Approvals valid for 12 months where 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 (i.e. the patient has walked 100 metres or more with or without aids in the last six months).

Note: Natalizumab can only be dispensed from a pharmacy registered in the Tysabri Australasian Prescribing Programme operated by the supplier. Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

136 MELATONIN - Special Authority see SA1666 - Retail pharmacy (brand switch fee removed) Brand switch fee payable (Pharmacode 2634112)

30

Tab modified-release 2 mg – No more than 5 tab per day....... 11.50

✓ Vigisom

Check your Schedule for full details	Subsidy	Brand or
Schedule page ref	(Mnfr's price)	Generic Mnfr
	\$ Per	✓ fully subsidised

147	AZACITIDINE – PCT only – Specialist – Special Authority see SA 2141 1467	(amended	Special Authority criteria)
	Inj 100 mg vial75.06	1	✓ Azacitidine Dr
			Reddy's
	605.00		✓ Vidaza
	Inj 1 mg for ECP0.83	1 mg	✓ Baxter

► SA2141 1467 Special Authority for Subsidy

Initial application only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - 1.1 The patient has International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome; or
 - 1.2 The patient has chronic myelomonocytic leukaemia (10%-29% marrow blasts without myeloproliferative disorder); or
 - 1.3 The patient has acute myeloid leukaemia with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation Classification (WHO); and
- 2 The patient has performance status (WHO/ECOG) grade 0-2; and
- 3 The patient does not have secondary myelodysplastic syndrome resulting from chemical injury or prior treatment with chemotherapy and/or radiation for other diseases; and
- 3 The patient has an estimated life expectancy of at least 3 months.

Renewal only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

Roth:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and patient is benefitting from treatment.
- 175 ADALIMUMAB (AMGEVITA) Special Authority see SA2142 2102 Retail pharmacy (amended Special Authority criteria affect criteria shown only)

Inj 20 mg per 0.4 ml prefilled syringe	190.00	1	✓ Amgevita
Inj 40 mg per 0.8 ml prefilled pen	375.00	2	✓ Amgevita
Inj 40 mg per 0.8 ml prefilled syringe	375.00	2	✓ Amgevita

► SA2142 2102 Special Authority for Subsidy

Initial application — (Behcet's disease - severe) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Fither:

- 1 The patient has previously had an approval for Humira; or
- 2 Roth.
 - 2.1 The patient has severe Behcet's disease* that is significantly impacting the patient's quality of life; and
 - 2.2 Either:
 - 2.2.1 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
 - 2.2.2 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) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

Check your Schedule for full details	Subsidy	Brand or
Schedule page ref	(Mnfr's price)	Generic Mnfr
	\$ Per	✓ fully subsidised

continued...

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 All of the following:
 - 2.1 Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas; and
 - 2.2 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
 - 2.3 Patient has 3 or more active lesions: and
 - 2.4 The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application.

Initial application — (Plaque psoriasis - severe chronic) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis: and
 - 2.1.2 Either:
 - 2.1.2.1 Patient has experienced intolerable side effects; or
 - 2.1.2.2 Patient has received insufficient benefit to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or
 - 2.2 All of the following:
 - 2.2.1 Either:
 - 2.2.1.1 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
 - 2.2.1.2 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; and
 - 2.2.2 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
 - 2.2.3 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.

Initial application — (pyoderma gangrenosum) only from a dermatologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Both:
 - 2.1 Patient has pyoderma gangrenosum*; and
 - 2.2 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.

Initial application — (Crohn's disease – adults) only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or

[▲] Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist

continued...

- 2 All of the following:
 - 2.1 Patient has severe active Crohn's disease: and
 - 2.2 Any of the following:
 - 2.2.1 Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10: or
 - 2.2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
 - 2.2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
 - 2.2.4 Patient has an ileostomy or colostomy and has intestinal inflammation; and
 - 2.3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
 - 2.4 Surgery (or further surgery) is considered to be clinically inappropriate.

Initial application — (Crohn's disease - children) only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira: or
- 2 All of the following:
 - 2.1 Paediatric patient has active Crohn's disease; and
 - 2.2 Either:
 - 2.2.1 Patient has a PCDAI score of greater than or equal to 30; or
 - 2.2.2 Patient has extensive small intestine disease; and
 - 2.3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
 - 2.4 Surgery (or further surgery) is considered to be clinically inappropriate.

Initial application — (Crohn's disease - fistulising) only from a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Fither:

- 1 The patient has previously had an approval for Humira; or
- 2 All of the following:
 - 2.1 Patient has confirmed Crohn's disease; and
 - 2.2 Any of the following:
 - 2.2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
 - 2.2.2 Patient has one or more rectovaginal fistula(e); or
 - 2.2.3 Patient has complex peri-anal fistula; and
 - 2.3 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application.

Initial application — (Ocular inflammation - chronic) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Either:
 - 2.1 The patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; or
 - 2.2 Both:
 - 2.2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
 - 2.2.2 Any of the following:
 - 2.2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
 - 2.2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or

Check your Schedule for full details	Subsidy	Brand or
Schedule page ref	(Mnfr's price)	Generic Mnfr
	\$ Per	✓ fully subsidised

continued...

2.2.2.3 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.

Initial application — (Ocular inflammation - severe) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Either:
 - 2.1 Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; or
 - 2.2 Both:
 - 2.2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
 - 2.2.2 Any of the following:
 - 2.2.2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or
 - 2.2.2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or
 - 2.2.2.3 Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms.

Initial application — (ankylosing spondylitis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1. The patient has previously had an approval for Humira; or
- 2. Either:
 - 2.1 Both:
 - 2.1.1 Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
 - 2.1.2 Either:
 - 2.1.2.1 The patient has experienced intolerable side effects; or
 - 2.1.2.2 The patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis; or
 - 2.2 All of the following:
 - 2.2.1 Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months; and
 - 2.2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
 - 2.2.3 Patient has bilateral sacroiliitis demonstrated by radiology imaging; and
 - 2.2.4 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
 - 2.2.5 Either:
 - 2.2.5.1 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
 - 2.2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender; and
 - 2.2.6 A BASDAI of at least 6 on a 010 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.

Initial application — (Arthritis - oligoarticular course juvenile idiopathic) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or

continued...

- 2 Either:
 - 2.1 Both:
 - 2.1.1 The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA); and
 - 2.1.2 Fither:
 - 2.1.2.1 Patient has experienced intolerable side effects: or
 - 2.1.2.2 Patient has received insufficient benefit to meet the renewal criteria for oligoarticular course JIA: or
 - 2.2 All of the following:
 - 2.2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
 - 2.2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and
 - 2.2.3 Either:
 - 2.2.3.1 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
 - 2.2.3.2 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).

Initial application — (Arthritis - polyarticular course juvenile idiopathic) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and
 - 2.1.2 Either:
 - 2.1.2.1 Patient has experienced intolerable side effects; or
 - 2.1.2.2 Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA; or
 - 2.2 All of the following:
 - 2.2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
 - 2.2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
 - 2.2.3 Any of the following:
 - 2.2.3.1 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
 - 2.2.3.2 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
 - 2.2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

Initial application — (Arthritis – psoriatic) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis; and

Check your Schedule for full details	Subsidy	Brand or
Schedule page ref	(Mnfr's price)	Generic Mnfr
	\$ Per	✓ fully subsidised

continued...

- 2.1.2 Either:
 - 2.1.2.1 The patient has experienced intolerable side effects: or
 - 2.1.2.2 The patient has received insufficient benefit from to meet the renewal criteria for psoriatic arthritis: or
- 2.2 All of the following:
 - 2.2.1 Patient has had active psoriatic arthritis for six months duration or longer; and
 - 2.2.2 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
 - 2.2.3 Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated); and
 - 2.2.4 Either:
 - 2.2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
 - 2.2.4.2 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
 - 2.2.5 Any of the following:
 - 2.2.5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 2.2.5.2 Patient has an ESR greater than 25 mm per hour; or
 - 2.2.5.3 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.

Initial application — (Arthritis - rheumatoid) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 Either:
 - 2.1 Both:
 - 2.1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
 - 2.1.2 Either:
 - 2.1.2.1 The patient has experienced intolerable side effects; or
 - 2.1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for rheumatoid arthritis: or
 - 2.2 All of the following:
 - 2.2.1 Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is CCP antibody positive) for six months duration or longer; and
 - 2.2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
 - 2.2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
 - 2.2.4 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
 - 225 Fither:
 - 2.2.5.1 Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin; or
 - 2.2.5.2 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate; and
 - 2.2.6 Either:
 - 2.2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or

continued...

2.2.6.2 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.

Initial application — (Still's disease - adult-onset (AOSD)) only from a rheumatologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or

- 2 Either:
 - 2.1 Both:
 - 2.1.1 The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for AOSD; and
 - 2.1.2 Either:
 - 2.1.2.1 Patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
 - 2.1.2.2 Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab; or
 - 2.2 All of the following:
 - 2.2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria; and
 - 2.2.2 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
 - 2.2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Initial application — (ulcerative colitis) only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or

- 2 All of the following:
 - 2.1 Patient has histologically confirmed ulcerative colitis; and
 - 2.2 Either:
 - 2.2.1 Patient's SCCAI score is greater than or equal to 4; or
 - 2.2.2 Patient's PUCAI score is greater than or equal to 65; and
 - 2.3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from prior therapy with immunomodulators and systemic corticosteroids; and
 - 2.4 Surgery (or further surgery) is considered to be clinically inappropriate.

Initial application — (undifferentiated spondyloarthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or

- 2 All of the following:
 - 2.1 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
 - 2.2 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
 - 2.3 Any of the following:
 - 2.3.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 2.3.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
 - 2.3.3 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

Check your Schedule for full details	Subsidy	Brand or
Schedule page ref	(Mnfr's price)	Generic Mnfr
	\$ Per	✓ fully subsidised

continued...

Initial application — (inflammatory bowel arthritis – axial) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 All of the following:
 - 2.1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
 - 2.2 Patient has axial inflammatory pain for six months or more; and
 - 2.3 Patient is unable to take NSAIDs: and
 - 2.4 Patient has bilateral sacroiliitis demonstrated by radiological imaging; and
 - 2.5 Patient has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
 - 2.6 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.

Initial application — (inflammatory bowel arthritis – peripheral) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 The patient has previously had an approval for Humira; or
- 2 All of the following:
 - 2.1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
 - 2.2 Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular; and
 - 2.3 Patient has tried and not responded to at least three months of methotrexate, or azathioprine at a maximum tolerated dose; and
 - 2.4 Patient has tried and not responded to at least three months of sulfasalazine at a maximum tolerated dose; and
 - 2.5 Any of the following:
 - 2.5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 2.5.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
 - 2.5.3 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.

199 PALIVIZUMAB – PCT only – Specialist – Special Authority see SA2143 2128 (amended Special Authority criteria – affected criteria shown only)

➤ SA2143 2128 Special Authority for Subsidy

Initial application — (RSV prophylaxis for the 2022/2023 RSV seasons, in the context of COVID-19) only from a paediatrician. Approvals valid for 6 months for applications meeting the following criteria: Either:

- 1 Infant was born in the last 2 years and has severe lung, airway, neurological or neuromuscular disease that requires ongoing, life-sustaining community ventilation; or
- 2 Both:
 - 2.1 Infant was born in the last 12 months; and
 - 2.2 Any of the following:
 - 2.2.1 Patient was born at less than 28 weeks gestation; or
 - 2.2.2 Both
 - 2.2.2.1 Patient was born at less than 32 weeks gestation; and
 - 2.2.2.2 Either:
 - 2.2.2.2.1 Patient has chronic lung disease; or
 - 2.2.2.2.2 Patient is Māori or any Pacific ethnicity; or
 - 2.2.3 Both:
 - 2.2.3.1 Patient has haemodynamically significant heart disease; and
 - 2.2.3.2 Any of the following:
 - 2.2.3.2.1 Patient has unoperated simple congenital heart disease with significant left to right shunt (see note a); or
 - 2.2.3.2.2 Patient has unoperated or surgically palliated complex congenital heart disease; or
 - 2.2.3.2.3 Patient has severe pulmonary hypertension (see note b); or
 - 2.2.3.2.4 Patient has moderate or severe LV failure (see note c).

Notes:

- a) Patient requires/will require heart failure medication, and/or patient has significant pulmonary hypertension, and/or patient will require surgical palliation/definitive repair within the next 3 months.
- b) Mean pulmonary artery pressure more than 2545 mmHg.
- c) LV Ejection Fraction less than 40%.

Check your Schedule for full details	Subsidy	Brand or
Schedule page ref	(Mnfr's price)	Generic Mnfr
	\$ Per	✓ fully subsidised

220 TRASTUZUMAB EMTANSINE – PCT only – Specialist – Special Authority see SA2144 1871 (amended Special Authority criteria)

Inj 100 mg vial	2,320.00	1	✓ Kadcyla
Inj 160 mg vial	3,712.00	1	✓ Kadcyla
Inj 1 mg for ECP	24.52	1 mg	✓ Baxter

➤ SA2144 1871 Special Authority for Subsidy

Initial application - (early breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has early breast cancer expressing HER2 IHC3+ or ISH+; and
- 2 Documentation of pathological invasive residual disease in the breast and/or auxiliary lymph nodes following completion of surgery; and
- 3 Patient has completed systemic neoadjuvant therapy with trastuzumab and chemotherapy prior to surgery; and
- 4 Disease has not progressed during neoadiuvant therapy; and
- 5 Patient has left ventricular ejection fraction of 45% or greater; and
- 6 Adjuvant treatment with trastuzumab emtansine to be commenced within 12 weeks of surgery; and
- 7 Trastuzumab emtansine to be discontinued at disease progression; and
- 8 Total adjuvant treatment duration must not exceed 42 weeks (14 cycles)

Initial application – (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
- 3 Either:
 - 3.1 The patient has received prior therapy for metastatic disease*; or
 - 3.2 The patient developed disease recurrence during, or within six months of completing adjuvant therapy*; and
- 4 Patient has a good performance status (ECOG 0-1); and
- 5 Either:
 - 5.1 Patient does not have symptomatic brain metastases; or
 - 5.2 Patient has brain metastases and has received prior local CNS therapy; and
- 6 Patient has not received prior funded trastuzumab emtansine treatment; and
- 7 Treatment to be discontinued at disease progression.

Renewal – (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine; and
- 2 Treatment to be discontinued at disease progression.

Note: *Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

[▲] Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist

Changes to Subsidy and Manufacturer's Price

Effective 1 July 2022

34	CALCITRIOL (‡ subsidy) * Cap 0.25 mcg * Cap 0.5 mcg		100 100	✓ Calcitriol-AFT ✓ Calcitriol-AFT
45	COMPOUND ELECTROLYTES (‡ subsidy) Powder for oral soln – Up to 5 sach available on a PSO	9.53	50	✓ Electral
49	AMIODARONE HYDROCHLORIDE (↓ subsidy) ▲ Tab 100 mg	4.49	30 30 10	✓ Aratac ✓ Aratac ✓ Max Health
65	DIMETHICONE (‡ subsidy) * Crm 5% pump bottle	4.30	500 ml 0P	✓ healthE Dimethicone 5%
66	DIMETHICONE (‡ subsidy) * Lotn 4%	4.25	200 ml 0P	✓ healthE Dimethicone 4% Lotion
75	OXYTOCIN WITH ERGOMETRINE MALEATE – Up to 5 inj availa Inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml ampoule		60 († subsidy 5) ✓ Syntometrine
79	FLUDROCORTISONE ACETATE (‡ subsidy) * Tab 100 mcg	11.46	100	✓ Florinef
89	CEFALEXIN († subsidy) Cap 500 mg	5.95	20	✓ Cephalexin ABM
118	PRAMIPEXOLE HYDROCHLORIDE (↓ subsidy) ▲ Tab 0.25 mg ▲ Tab 1 mg		100 100	✓ Ramipex ✓ Ramipex
122	MORPHINE HYDROCHLORIDE († subsidy) a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing frought of the properties of the p	equency 11.98	200 ml	√ RA-Morph
130	CYCLIZINE LACTATE (\$\ddot \text{ subsidy}) Inj 50 mg per ml, 1 ml ampoule	16.36	10	✓ HameIn

Check your Schedule for full details	Subsidy	Brand or
Schedule page ref	(Mnfr's price)	Generic Mnfr
	\$ Per	✓ fully subsidised

Changes to Subsidy and Manufacturer's Price – effective 1 July 2022 (continued)

141	BUPRENORPHINE WITH NALOXONE – Special Authority see SA1203 – Re a) No patient co-payment payable b) Safety medicine; prescriber may determine dispensing frequency	tail pharmac	y (↓ subsidy)
	Tab sublingual 2 mg with naloxone 0.5 mg11.76	28	✓ Buprenorphine Naloxone BNM
	Tab sublingual 8 mg with naloxone 2 mg34.00	28	✓ Buprenorphine Naloxone BNM
149	MERCAPTOPURINE (‡ subsidy)		
	Tab 50 mg – PCT – Retail pharmacy-Specialist25.90	25	✓ Puri-nethol
233	MONTELUKAST (‡ subsidy)		
	* Tab 4 mg	28	✓ Montelukast Mylan
	* Tab 5 mg	28	✓ Montelukast Mylan
	* Tab 10 mg2.90	28	✓ Montelukast Mylan
236	CHLORAMPHENICOL (↓ subsidy)		
	Eye oint 1%1.09	5 g OP	✓ Devatis
240	OLOPATADINE (↓ subsidy)		
	Eve drops 0.1%	5 ml 0P	Olopatadine Teva

Delisted Items

Effective 1 July 2022

34	CALCIUM CARBONATE * Tab eff 1.25 g (500 mg elemental) - Subsidy by endorsement	54.60	76	✓ Cacit S29
35	CALCIUM LACTATE GLUCONATE WITH CALCIUM CARBONATE Tab eff 2.94 g with calcium carbonate 0.3 g (500 mg elemental) — Subsidy by endorsement		20	✓ Calcium-Sandoz
			100	Forte Calcium-Sandoz
	Subsidy by endorsement – Only when prescribed for paediate carbonate oral liquid is considered unsuitable.	ric patients ((< 5 yea	Forte rs) where calcium
93	PHENOXYMETHYLPENICILLIN (PENICILLIN V) Cap 250 mg – Up to 30 cap available on a PS0 Note – this delist applies to Pharmacode 2048841	3.84	50	✓ Cilicaine VK
123	OXYCODONE HYDROCHLORIDE a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing freque Inj 10 mg per ml, 1 ml ampoule		5	✓ OxyNorm
	Inj 10 mg per ml, 2 ml ampoule		5 5	✓ OxyNorm ✓ OxyNorm
		00.00	J	Oxymoniii
130	BETAHISTINE DIHYDROCHLORIDE * Tab 16 mg	2 00	84	✓ Vergo 16
	* Tab To Hig	3.00	04	Vergo 10
147	AZACITIDINE – PCT only – Specialist – Special Authority see SA21			
	Inj 100 mg vial60	15.00	1	✓Vidaza
163	SUNITINIB – Special Authority see SA2117 – Retail pharmacy			
	Cap 12.5 mg2,31		28	✓ Sutent
	Cap 25 mg4,63		28	✓ Sutent
	Cap 50 mg9,26	61.54	28	✓ Sutent
241	PHARMACY SERVICES May only be claimed once per patient.			
	* Brand switch fee	4.50	1 fee	✓ BSF Cinacalcet Devatis ✓ BSF Comtan ✓ BSF Vigisom
	a) The Pharmacode for BSF Vigisom is 2634112			-

c) The Pharmacode for BSF Comtan is 2634139

Check your Schedule for full details	Subsidy	Brand or
Schedule page ref	(Mnfr's price)	Generic Mnfr
	\$ Per	✓ fully subsidised

Items to be Delisted

Effective 1 December 2022

100	TENOFOVIR DISOPROXIL Tenofovir disoproxil prescribed under endorsement for the subsidised antiretrovirals for the purposes of Special Autho	rity SA2139.		·
	* Tab 245 mg (300.6 mg as a succinate)	38.10	30	✓ Tenofovir Disoproxil Teva
102	EMTRICITABINE WITH TENOFOVIR DISOPROXIL – Subsidy by see SA2138 Endorsement for treatment of HIV: Prescription is deemed to disoproxil is co-prescribed with another antiretroviral subsicular prescription is annotated accordingly by the Pharmacist or Note: Emtricitabine with tenofovir disoproxil prescribed und included in the count of up to 4 subsidised antiretrovirals, at the purposes of Special Authority SA2139. There is an apprescribe antiretroviral therapy in New Zealand. Further info Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate)	to be endorsed dised under Sendorsed by ler endorsem and counts as roval process rmation is av	ed if emtricit Special Auth the prescrib ent for the to s two antiret s to become	abine with tenofovir ority SA2139 and the per. reatment of HIV is roviral medications, for a named specialist to
400		01.13	50	V IGVa
130	METOCLOPRAMIDE HYDROCHLORIDE * Inj 5 mg per ml, 2 ml ampoule - Up to 5 inj available on a PSO	9.50	10	✓ Pfizer
183	ADALIMUMAB (HUMIRA) – Special Authority see SA2101 – R Inj 20 mg per 0.4 ml prefilled syringe		cy 2	✓ Humira
241	ACETYLCYSTEINE Inj 200 mg per ml, 10 ml ampoule	58.76	10	✓ DBL Acetylcysteine ✓ Martindale Pharma S29
	Note – Martindale Pharma delist applies to Pharmacode 2318	857.		
Effec	tive 1 July 2023			
229	EFORMOTEROL FUMARATE Powder for inhalation, 12 mcg per dose, and monodose device	20.64 (35.80)	60 dose	Foradil
Effec	tive 1 August 2023			
236	GENTAMICIN SULPHATE Eye drops 0.3%	11.40	5 ml 0P	✓ Genoptic

Index

Pharmaceuticals and brands

A	
Acetylcysteine19,	39
Adalimumab (Amgevita)	26
Adalimumab (Humira) 19,	39
Amgevita	26
Amiodarone hydrochloride	36
Antiretrovirals	
Aratac	
Azacitidine	
Azacitidine Dr Reddy's	26
B	20
Betahistine dihydrochloride	20
BSF Cinacalcet Devatis	30
BSF Comtan	
BSF Vigisom	30
Buprenorphine Naloxone BNM	07
Buprenorphine with naloxone	37
C .	~~
Cacit	
Calcitriol	
Calcitriol-AFT	
Calcium carbonate	
Calcium lactate gluconate with calcium carbonate	
Calcium-Sandoz Forte	
Cefalexin	
Cephalexin ABM	
Chloramphenicol	37
Cilicaine VK	38
Cinacalcet	22
Cinacalet Devatis	22
Compound electrolytes	36
Comtan	24
Cyclizine lactate	
D	
DBL Acetylcysteine	39
Dimethicone	
Docusate sodium with sennosides	
F	
Eformoterol fumarate	39
Electral	
Elelyso	
Emtricitabine with tenofovir disoproxil 19, 22,	
Entacapone	
F	27
Florinef	36
Fludrocortisone acetate	36
Foradil	
G	აყ
	40
Gemtuzumab ozogamicin	19
Genoptic	ა 9

Gentamicin sulphate 4	39
nealthE Dimethicone 4% Lotion	36
nealthE Dimethicone 5%	
Humira19,	39
(
Kadcyla	35
<u> </u>	
_axsol	20
W	
Macrobid	
Melatonin	25
Mercaptopurine	3/
Metoclopramide hydrochloride	
Montelukast Montelukast Mylan	37
Morphine hydrochloride	. J1
Multiple Sclerosis Treatments	25
Mylotarg	
V	. 13
Nevirapine	24
Nitrofurantoin	
)	
Olopatadine	37
Olopatadine Teva	
Oxycodone hydrochloride	38
OxyNorm	
Oxytocin with ergometrine maleate 22,	36
Palivizumab	
Pharmacy services	38
Phenoxymethylpenicillin (Penicillin V)	38
Pramipexole hydrochloride	36
Puri-nethol	37
R Ramipex	00
Ramipex	36
RA-Morph s	30
S Sunitinib	20
Sutent	
Synagis	
Syntometrine22,	
r	00
raliglucerase alfa	20
Fenofovir disoproxil	
Fenofovir Disoproxil Emtricitabine Mylan 19,	
Tenofovir Disoproxil Mylan	19
Tenofovir Disoproxil Teva	39
Frastuzumab emtansine	

Index

Pharmaceuticals and brands

V	Vigisom
Vergo 16 38	Viramune Suspension
Vidaza 26, 38	

New Zealand Permit No. 478



Pharmaceutical Management Agency Level 9, 40 Mercer Street, PO Box 10254, Wellington 6143, New Zealand Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz Email: enquiry@pharmac.govt.nz

ISSN 1172-9376 (Print) ISSN 1179-3686 (Online)

Te Kāwanatanga o Aotearoa New Zealand Government

While care has been taken in compiling this Update, Pharmaceutical Management Agency takes no responsibility for any errors or omissions and shall not be liable to any person for any damages or loss arising out of reliance by that person for any purpose on any of the contents of this Update. Errors and omissions brought to the attention of Pharmaceutical Management Agency will be corrected if necessary by an erratum or otherwise in the next edition of the update.

If Undelivered, Return To: PO Box 10254, Wellington 6143, New Zealand