



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 February 2022



Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 February 2022 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$7.78
	Dangerous drug fee	\$4.82
	Extemporaneously-prepared	\$9.82
	Allowable additional patient charge*	\$4.54
Additional Fees (for safety net prices):	Ready-prepared	\$1.30
	Extemporaneously-prepared	\$1.67
Patient Co-payments:	General	\$42.50
	Concessional	\$6.80
Safety Net Thresholds:	General	\$1542.10
	Concessional	\$326.40
Safety Net Card Issue Fee:		\$10.65

* The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the Safety Net threshold.

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 February 2022. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Prescriber Bag

Deletions

Deletion – Item

12616B **ADRENALINE (EPINEPHRINE)**, adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 10 x 1 mL ampoules
(*ADRENALINE RENAUDIN*)

General Pharmaceutical Benefits

Additions

Addition – Item

12826C **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56 (*Calquence*)
12830G **LEVOTHYROXINE**, levothyroxine sodium 125 microgram tablet, 200 (*Eltroxin*)
12828E **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 (*Rinvoq*)
12831H **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 (*Rinvoq*)
12835M **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 (*Rinvoq*)
12827D **UPADACITINIB**, upadacitinib 30 mg modified release tablet, 28 (*Rinvoq*)
12829F **UPADACITINIB**, upadacitinib 30 mg modified release tablet, 28 (*Rinvoq*)
12836N **UPADACITINIB**, upadacitinib 30 mg modified release tablet, 28 (*Rinvoq*)

Addition – Brand

1354G *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 20 mg tablet, 60
1354G *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 20 mg tablet, 60
2478K *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 20 mg tablet, 60
2478K *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 20 mg tablet, 60
9125G *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 20 mg tablet, 60
9125G *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 20 mg tablet, 60
1381Q *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 50 mg tablet, 60
1381Q *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 50 mg tablet, 60
2482P *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 50 mg tablet, 60
2482P *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 50 mg tablet, 60
9126H *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 50 mg tablet, 60
9126H *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 50 mg tablet, 60
1415L *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 70 mg tablet, 60
1415L *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 70 mg tablet, 60
2485T *Dasatinib ARX, XT* – **DASATINIB**, dasatinib 70 mg tablet, 60
2485T *Dasatinib Dr.Reddy's, RI* – **DASATINIB**, dasatinib 70 mg tablet, 60

9127J	<i>Dasatinib ARX, XT</i> – DASATINIB , dasatinib 70 mg tablet, 60
9127J	<i>Dasatinib Dr.Reddy's, RI</i> – DASATINIB , dasatinib 70 mg tablet, 60
1416M	<i>Dasatinib ARX, XT</i> – DASATINIB , dasatinib 100 mg tablet, 30
1416M	<i>Dasatinib Dr.Reddy's, RI</i> – DASATINIB , dasatinib 100 mg tablet, 30
9342Q	<i>Dasatinib ARX, XT</i> – DASATINIB , dasatinib 100 mg tablet, 30
9342Q	<i>Dasatinib Dr.Reddy's, RI</i> – DASATINIB , dasatinib 100 mg tablet, 30
9343R	<i>Dasatinib ARX, XT</i> – DASATINIB , dasatinib 100 mg tablet, 30
9343R	<i>Dasatinib Dr.Reddy's, RI</i> – DASATINIB , dasatinib 100 mg tablet, 30
2896K	<i>Pharmacor Dimethyl Fumarate, CR</i> – DIMETHYL FUMARATE , dimethyl fumarate 120 mg enteric capsule, 14
2943X	<i>Pharmacor Dimethyl Fumarate, CR</i> – DIMETHYL FUMARATE , dimethyl fumarate 120 mg enteric capsule, 14
2966D	<i>Pharmacor Dimethyl Fumarate, CR</i> – DIMETHYL FUMARATE , dimethyl fumarate 240 mg enteric capsule, 56
8700X	<i>NOUMED ESCITALOPRAM, VO</i> – ESCITALOPRAM , escitalopram 10 mg tablet, 28
9432K	<i>NOUMED ESCITALOPRAM, VO</i> – ESCITALOPRAM , escitalopram 10 mg tablet, 28
8701Y	<i>NOUMED ESCITALOPRAM, VO</i> – ESCITALOPRAM , escitalopram 20 mg tablet, 28
9433L	<i>NOUMED ESCITALOPRAM, VO</i> – ESCITALOPRAM , escitalopram 20 mg tablet, 28
11408K	<i>Ezetimibe GH, GQ</i> – EZETIMIBE , ezetimibe 10 mg tablet, 30
11408K	<i>Ezetimibe Sandoz, SZ</i> – EZETIMIBE , ezetimibe 10 mg tablet, 30
9483D	<i>EZEVYT 10/10, LR</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 10 mg tablet, 30
9484E	<i>EZEVYT 10/20, LR</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 20 mg tablet, 30
8881K	<i>EZEVYT 10/40, LR</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 40 mg tablet, 30
8882L	<i>EZEVYT 10/80, LR</i> – EZETIMIBE + SIMVASTATIN , ezetimibe 10 mg + simvastatin 80 mg tablet, 30
1433K	<i>FLUDROCORTISONE MEDSURGE, DZ</i> – FLUDROCORTISONE ACETATE , fludrocortisone acetate 100 microgram tablet, 100
12300J	<i>FULVESTRANT EVER PHARMA, IT</i> – FULVESTRANT , fulvestrant 250 mg/5 mL injection, 2 x 5 mL syringes
10416F	<i>GLATIRAMER ACETATE-TEVA, EV</i> – GLATIRAMER ACETATE , glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes
10416F	<i>Glatira, JU</i> – GLATIRAMER ACETATE , glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes
11625W	<i>Revive Tears, PP</i> – HYPROMELLOSE , hypromellose 0.3% w/w eye drops, 10 mL
11634H	<i>Revive Tears, PP</i> – HYPROMELLOSE , hypromellose 0.3% w/w eye drops, 10 mL
11643T	<i>Revive Tears, PP</i> – HYPROMELLOSE , hypromellose 0.3% w/w eye drops, 10 mL
12709X	<i>Imatinib-APOTEX, TX</i> – IMATINIB , imatinib 100 mg capsule, 60
12722N	<i>Imatinib-APOTEX, TX</i> – IMATINIB , imatinib 100 mg capsule, 60
12723P	<i>Imatinib-APOTEX, TX</i> – IMATINIB , imatinib 400 mg capsule, 30
12754G	<i>Imatinib-APOTEX, TX</i> – IMATINIB , imatinib 400 mg capsule, 30
2174K	<i>Eltroxin, LT</i> – LEVOTHYROXINE , levothyroxine sodium 50 microgram tablet, 200
2174K	<i>LEVOXINE, RA</i> – LEVOTHYROXINE , levothyroxine sodium 50 microgram tablet, 200
9287T	<i>Eltroxin, LT</i> – LEVOTHYROXINE , levothyroxine sodium 75 microgram tablet, 200
9287T	<i>LEVOXINE, RA</i> – LEVOTHYROXINE , levothyroxine sodium 75 microgram tablet, 200
2175L	<i>Eltroxin, LT</i> – LEVOTHYROXINE , levothyroxine sodium 100 microgram tablet, 200
2175L	<i>LEVOXINE, RA</i> – LEVOTHYROXINE , levothyroxine sodium 100 microgram tablet, 200
2173J	<i>Eltroxin, LT</i> – LEVOTHYROXINE , levothyroxine sodium 200 microgram tablet, 200
2173J	<i>LEVOXINE, RA</i> – LEVOTHYROXINE , levothyroxine sodium 200 microgram tablet, 200
1824B	<i>FEMIN, LI</i> – MEFENAMIC ACID , mefenamic acid 250 mg capsule, 50
9353G	<i>Mesalazine 1.2 TAKEDA, NQ</i> – MESALAZINE , mesalazine 1.2 g modified release tablet, 60

2387P	<i>METHYLPHENIDATE-TEVA XR, TB</i> – METHYLPHENIDATE , methylphenidate hydrochloride 18 mg modified release tablet, 30
2172H	<i>METHYLPHENIDATE-TEVA XR, TB</i> – METHYLPHENIDATE , methylphenidate hydrochloride 27 mg modified release tablet, 30
2388Q	<i>METHYLPHENIDATE-TEVA XR, TB</i> – METHYLPHENIDATE , methylphenidate hydrochloride 36 mg modified release tablet, 30
2432B	<i>METHYLPHENIDATE-TEVA XR, TB</i> – METHYLPHENIDATE , methylphenidate hydrochloride 54 mg modified release tablet, 30
8513C	<i>NOUMED MIRTAZAPINE, VO</i> – MIRTAZAPINE , mirtazapine 30 mg tablet, 30
8883M	<i>NOUMED MIRTAZAPINE, VO</i> – MIRTAZAPINE , mirtazapine 45 mg tablet, 30
1692C	<i>Nitrofurantoin BNM, BZ</i> – NITROFURANTOIN , nitrofurantoin 50 mg capsule, 30
1693D	<i>Nitrofurantoin BNM, BZ</i> – NITROFURANTOIN , nitrofurantoin 100 mg capsule, 30
12023T	<i>Oxyndone, TX</i> – OXYCODONE , oxycodone hydrochloride 5 mg tablet, 20
12048D	<i>Oxyndone, TX</i> – OXYCODONE , oxycodone hydrochloride 5 mg tablet, 20
2622B	<i>Oxyndone, TX</i> – OXYCODONE , oxycodone hydrochloride 5 mg tablet, 20
5195K	<i>Oxyndone, TX</i> – OXYCODONE , oxycodone hydrochloride 5 mg tablet, 20
8355R	<i>NOUMED TELMISARTAN, VO</i> – TELMISARTAN , telmisartan 40 mg tablet, 28
8356T	<i>NOUMED TELMISARTAN, VO</i> – TELMISARTAN , telmisartan 80 mg tablet, 28
8163P	<i>NOUMED TOPIRAMATE, VO</i> – TOPIRAMATE , topiramate 25 mg tablet, 60
8164Q	<i>NOUMED TOPIRAMATE, VO</i> – TOPIRAMATE , topiramate 50 mg tablet, 60
8165R	<i>NOUMED TOPIRAMATE, VO</i> – TOPIRAMATE , topiramate 100 mg tablet, 60
8166T	<i>NOUMED TOPIRAMATE, VO</i> – TOPIRAMATE , topiramate 200 mg tablet, 60

Addition – Equivalence Indicator

2896K	<i>Tecfidera, BD</i> – DIMETHYL FUMARATE , dimethyl fumarate 120 mg enteric capsule, 14
2943X	<i>Tecfidera, BD</i> – DIMETHYL FUMARATE , dimethyl fumarate 120 mg enteric capsule, 14
2966D	<i>Tecfidera, BD</i> – DIMETHYL FUMARATE , dimethyl fumarate 240 mg enteric capsule, 56
1433K	<i>Florinef, AS</i> – FLUDROCORTISONE ACETATE , fludrocortisone acetate 100 microgram tablet, 100
10416F	<i>Copaxone, TB</i> – GLATIRAMER ACETATE , glatiramer acetate 40 mg/mL injection, 12 x 1 mL syringes
1824B	<i>Ponstan, PF</i> – MEFENAMIC ACID , mefenamic acid 250 mg capsule, 50
9353G	<i>Mezavant, TK</i> – MESALAZINE , mesalazine 1.2 g modified release tablet, 60

Addition – Note

11419B	IBRUTINIB , ibrutinib 140 mg capsule, 120 (<i>Imbruvica</i>)
2174K	LEVOTHYROXINE , levothyroxine sodium 50 microgram tablet, 200 (<i>Eltroxin, Eutroxsig, LEVOXINE, Oroxine</i>)
9287T	LEVOTHYROXINE , levothyroxine sodium 75 microgram tablet, 200 (<i>Eltroxin, Eutroxsig, LEVOXINE, Oroxine</i>)
2175L	LEVOTHYROXINE , levothyroxine sodium 100 microgram tablet, 200 (<i>Eltroxin, Eutroxsig, LEVOXINE, Oroxine</i>)
2173J	LEVOTHYROXINE , levothyroxine sodium 200 microgram tablet, 200 (<i>Eltroxin, Eutroxsig, LEVOXINE, Oroxine</i>)

Deletions

Deletion – Item

12617C	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 10 x 1 mL ampoules (<i>ADRENALINE RENAUDIN</i>)
12618D	ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 10 x 1 mL ampoules (<i>ADRENALINE RENAUDIN</i>)
10647J	RIBAVIRIN , ribavirin 400 mg tablet, 28 (<i>Ibavyr</i>)
10673R	RIBAVIRIN , ribavirin 400 mg tablet, 28 (<i>Ibavyr</i>)
10665H	RIBAVIRIN , ribavirin 600 mg tablet, 28 (<i>Ibavyr</i>)
10666J	RIBAVIRIN , ribavirin 600 mg tablet, 28 (<i>Ibavyr</i>)

Deletion – Brand

8358X	<i>Clopidogrel Sandoz, SZ</i> – CLOPIDOGREL , clopidogrel 75 mg tablet, 28
9317J	<i>Clopidogrel Sandoz, SZ</i> – CLOPIDOGREL , clopidogrel 75 mg tablet, 28
11815W	<i>Semglee, AF</i> – INSULIN GLARGINE , insulin glargine 100 units/mL injection, 5 x 3 mL pen devices
1558B	<i>Isomonit, SZ</i> – ISOSORBIDE MONONITRATE , isosorbide mononitrate 60 mg modified release tablet, 30
1906H	<i>Adefin XL 30, AF</i> – NIFEDIPINE , nifedipine 30 mg modified release tablet, 30
1907J	<i>Adefin XL 60, AF</i> – NIFEDIPINE , nifedipine 60 mg modified release tablet, 30
1898X	<i>Feldene, PF</i> – PIROXICAM , piroxicam 20 mg capsule, 25
5204X	<i>Feldene, PF</i> – PIROXICAM , piroxicam 20 mg capsule, 25
1978D	<i>Rani 2, AF</i> – RANITIDINE , ranitidine 150 mg tablet, 60
1977C	<i>Rani 2, AF</i> – RANITIDINE , ranitidine 300 mg tablet, 30

Deletion – Equivalence Indicator

1016L	<i>Link Medical Products Pty Ltd, LM</i> – ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules
5004J	<i>Link Medical Products Pty Ltd, LM</i> – ADRENALINE (EPINEPHRINE) , adrenaline (epinephrine) 1 in 1000 (1 mg/mL) injection, 5 x 1 mL ampoules
11815W	<i>Optisulin SoloStar, WA</i> – INSULIN GLARGINE , insulin glargine 100 units/mL injection, 5 x 3 mL pen devices

Deletion – Note

2896K	DIMETHYL FUMARATE , dimethyl fumarate 120 mg enteric capsule, 14 (<i>Pharmacor Dimethyl Fumarate, Tecfidera</i>)
2943X	DIMETHYL FUMARATE , dimethyl fumarate 120 mg enteric capsule, 14 (<i>Pharmacor Dimethyl Fumarate, Tecfidera</i>)
2966D	DIMETHYL FUMARATE , dimethyl fumarate 240 mg enteric capsule, 56 (<i>Pharmacor Dimethyl Fumarate, Tecfidera</i>)
11815W	INSULIN GLARGINE , insulin glargine 100 units/mL injection, 5 x 3 mL pen devices (<i>Optisulin SoloStar,)</i>
9039R	INSULIN GLARGINE , insulin glargine 100 units/mL injection, 5 x 3 mL cartridges (<i>Optisulin</i>)

Alterations

Alteration – Brand Name

<i>From</i>	
12683M	<i>Darzalex, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
<i>To</i>	
12683M	<i>Darzalex SC, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
<i>From</i>	
12704P	<i>Darzalex, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
<i>To</i>	
12704P	<i>Darzalex SC, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
<i>From</i>	
12725R	<i>Darzalex, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
<i>To</i>	
12725R	<i>Darzalex SC, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
<i>From</i>	
12755H	<i>Darzalex, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial
<i>To</i>	
12755H	<i>Darzalex SC, JC</i> – DARATUMUMAB , daratumumab 1.8 g/15 mL injection, 15 mL vial

Alteration – Restriction

12291X	DUPILUMAB , dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes (<i>Dupixent</i>)
12292Y	DUPILUMAB , dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes (<i>Dupixent</i>)
11419B	IBRUTINIB , ibrutinib 140 mg capsule, 120 (<i>Imbruvica</i>)

Alteration – Manufacturer Code

2923W	<i>Rythmodan</i> – DISOPYRAMIDE , disopyramide 100 mg capsule, 100	<i>From</i> SW	<i>To</i> PB
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11677N	<i>Acimax Tablets</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30	AL	FJ
12270T	<i>Acimax Tablets</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30	AL	FJ
9109K	<i>Acimax Tablets</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30	AL	FJ
9110L	<i>Acimax Tablets</i> – OMEPRAZOLE , omeprazole 20 mg enteric tablet, 30	AL	FJ

Advance Notices

1 March 2022

Deletion – Brand

12336G	<i>Humira, VE</i> – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 4 x 0.4 mL pen devices
12343P	<i>Humira, VE</i> – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL pen devices
12344Q	<i>Humira, VE</i> – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL syringes
12346T	<i>Humira, VE</i> – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL pen devices
12392F	<i>Humira, VE</i> – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL syringes
12404W	<i>Humira, VE</i> – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL syringes
12418N	<i>Humira, VE</i> – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 4 x 0.4 mL pen devices
12427C	<i>Humira, VE</i> – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL syringes
12441T	<i>Humira, VE</i> – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL pen devices
12445B	<i>Humira, VE</i> – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL pen devices
12452J	<i>Humira, VE</i> – ADALIMUMAB , adalimumab 40 mg/0.4 mL injection, 6 x 0.4 mL pen devices
8295N	<i>Candesartan Aspen 4, RW</i> – CANDESARTAN , candesartan cilexetil 4 mg tablet, 30
8296P	<i>Candesartan Aspen 8, RW</i> – CANDESARTAN , candesartan cilexetil 8 mg tablet, 30
8297Q	<i>Candesartan Aspen 16, RW</i> – CANDESARTAN , candesartan cilexetil 16 mg tablet, 30
8889W	<i>Candesartan Aspen 32, RW</i> – CANDESARTAN , candesartan cilexetil 32 mg tablet, 30
8504N	<i>Candesartan Combi Aspen 16/12.5, RW</i> – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
9314F	<i>Candesartan Combi Aspen 32/12.5, RW</i> – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
9315G	<i>Candesartan Combi Aspen 32/25, RW</i> – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
1759N	<i>DBL Cefotaxime, PF</i> – CEFOTAXIME , cefotaxime 2 g injection, 10 vials
1769D	<i>DBL Cefotaxime, PF</i> – CEFOTAXIME , cefotaxime 2 g injection, 10 vials
1834M	<i>Gabapentin Aspen 300, RW</i> – GABAPENTIN , gabapentin 300 mg capsule, 100
1835N	<i>Gabapentin Aspen 400, RW</i> – GABAPENTIN , gabapentin 400 mg capsule, 100
8389M	<i>Gabapentin Aspen 800, RW</i> – GABAPENTIN , gabapentin 800 mg tablet, 100
8505P	<i>Gabapentin Aspen 100, RW</i> – GABAPENTIN , gabapentin 100 mg capsule, 100
8559L	<i>Gabapentin Aspen 600, RW</i> – GABAPENTIN , gabapentin 600 mg tablet, 100
2848X	<i>Lamotrigine Aspen 25, RW</i> – LAMOTRIGINE , lamotrigine 25 mg tablet, 56
2849Y	<i>Lamotrigine Aspen 50, RW</i> – LAMOTRIGINE , lamotrigine 50 mg tablet, 56
2850B	<i>Lamotrigine Aspen 100, RW</i> – LAMOTRIGINE , lamotrigine 100 mg tablet, 56
2851C	<i>Lamotrigine Aspen 200, RW</i> – LAMOTRIGINE , lamotrigine 200 mg tablet, 56
8063J	<i>Lamotrigine Aspen 5, RW</i> – LAMOTRIGINE , lamotrigine 5 mg tablet, 56
11508Q	<i>Methoblastin PFS, PF</i> – METHOTREXATE , methotrexate 15 mg/0.6 mL injection, 4 x 0.6 mL syringes
11509R	<i>Methoblastin PFS, PF</i> – METHOTREXATE , methotrexate 20 mg/0.8 mL injection, 4 x 0.8 mL syringes
11525N	<i>Methoblastin PFS, PF</i> – METHOTREXATE , methotrexate 7.5 mg/0.3 mL injection, 4 x 0.3 mL syringes
11526P	<i>Methoblastin PFS, PF</i> – METHOTREXATE , methotrexate 10 mg/0.4 mL injection, 4 x 0.4 mL syringes
11544N	<i>Methoblastin PFS, PF</i> – METHOTREXATE , methotrexate 25 mg/mL injection, 4 x 1 mL syringes

- 2774B *Brevinor, PF* – **NORETHISTERONE + ETHINYLESTRADIOL**, norethisterone 500 microgram + ethinylestradiol 35 microgram tablet [21] (& inert substance tablet [7], 4 x 28
- 5442K *TOBRAMYCIN WOCKHARDT, WC* – **TOBRAMYCIN**, tobramycin 300 mg/5 mL inhalation solution, 56 x 5 mL ampoules

1 April 2022

Deletion – Brand

- 8748K *Edecrin, FK* – **ETACRYNIC ACID**, etacrynic acid 25 mg tablet, 100
- 8450R *Dimirel, AV* – **GLIMEPIRIDE**, glimepiride 1 mg tablet, 30
- 1621H *Metronide 400, AV* – **METRONIDAZOLE**, metronidazole 400 mg tablet, 21
- 5155H *Metronide 400, AV* – **METRONIDAZOLE**, metronidazole 400 mg tablet, 21

1 May 2022

Deletion – Brand

- 1324Q *Lopresor 50, NV* – **METOPROLOL TARTRATE**, METOPROLOL TARTRATE Tablet 50 mg, 100
- 1325R *Lopresor 100, NV* – **METOPROLOL TARTRATE**, METOPROLOL TARTRATE Tablet 100 mg, 60

Highly Specialised Drugs Program (Private Hospital)

Deletions

Deletion – Item

- 10623D **RIBAVIRIN**, ribavirin 400 mg tablet, 28 (*Ibavyr*)
- 10635R **RIBAVIRIN**, ribavirin 400 mg tablet, 28 (*Ibavyr*)
- 10637W **RIBAVIRIN**, ribavirin 600 mg tablet, 28 (*Ibavyr*)
- 10675W **RIBAVIRIN**, ribavirin 600 mg tablet, 28 (*Ibavyr*)

Deletion – Brand

- 12784W *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
- 6100C *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
- 6138C *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
- 12139X *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
- 12143D *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
- 12148J *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
- 6429J *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
- 12146G *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 125 mg tablet, 60
- 6430K *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 125 mg tablet, 60
- 6363X *Fulphila, AF* – **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

Alterations

Alteration – Note

- 6363X **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (*Neulasta, Pelgraz, Ristempa, Tezmota, Ziextenzo*)

Alteration – Manufacturer Code

- | | | | |
|-------|--|------------|----------|
| 6249X | <i>Caelyx</i> – DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL) , doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial | From
JC | To
BX |
|-------|--|------------|----------|

Highly Specialised Drugs Program (Public Hospital)

Deletions

Deletion – Item

- 10646H **RIBAVIRIN**, ribavirin 400 mg tablet, 28 (*Ibavyr*)
- 10678B **RIBAVIRIN**, ribavirin 400 mg tablet, 28 (*Ibavyr*)

- 10638X **RIBAVIRIN**, ribavirin 600 mg tablet, 28 (*Ibavyr*)
 10663F **RIBAVIRIN**, ribavirin 600 mg tablet, 28 (*Ibavyr*)

Deletion – Brand

- 12771E *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
 9597D *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
 9598E *Celazadine, CJ* – **AZACITIDINE**, azacitidine 100 mg injection, 1 vial
 12134P *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
 12140Y *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
 12145F *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
 5618Q *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 62.5 mg tablet, 60
 12149K *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 125 mg tablet, 60
 5619R *Bosentan Sandoz, SZ* – **BOSENTAN**, bosentan 125 mg tablet, 60
 9514R *Fulphila, AF* – **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

Alterations

Alteration – Note

- 9514R **PEGFILGRASTIM**, pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe (*Neulasta, Pelgraz, Ristempa, Tezmota, Ziextenzo*)

Alteration – Manufacturer Code

- | | | | |
|-------|---|-------------------|-----------------|
| 5705G | <i>Caelyx</i> – DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL) ,
doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial | <i>From</i>
JC | <i>To</i>
BX |
|-------|---|-------------------|-----------------|

Highly Specialised Drugs Program (Community Access)

Deletions

Deletion – Item

- 11657M **ATAZANAVIR**, atazanavir 300 mg capsule, 60 (*Atazanavir Mylan*)

Deletion – Brand

- 10349Q *Atazanavir Mylan, AF* – **ATAZANAVIR**, atazanavir 200 mg capsule, 60

Deletion – Equivalence Indicator

- 10349Q *Reyataz, BQ* – **ATAZANAVIR**, atazanavir 200 mg capsule, 60
 10321F *Reyataz, BQ* – **ATAZANAVIR**, atazanavir 300 mg capsule, 30

Repatriation Pharmaceutical Benefits

Additions

Addition – Item

- 12832J **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 10 cm x 13 cm dressing, 50 (*Mesorb 677001*)
 12825B **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 10 cm x 23 cm dressing, 50 (*Mesorb 677401*)
 12837P **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 12.5 cm x 12.5 cm hydroactive dressing, 10 (*Mextra Superabsorbent 610000*)
 12834L **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 17.5 cm x 22.5 cm hydroactive dressing, 10 (*Mextra Superabsorbent 610300*)
 12833K **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 22.5 cm x 32.5 cm hydroactive dressing, 10 (*Mextra Superabsorbent 610500*)
 12824Y **DRESSING NON-ADHERENT ABSORBENT**, dressing non-adherent absorbent 23 cm x 25 cm dressing, 30 (*Mesorb 677701*)

Deletions

Deletion – Item

- 12798N **DRESSING FOAM HEAVY EXUDATE**, dressing foam heavy exudate 10 cm x 13 cm dressing, 50 (*Mesorb 677001*)
- 12793H **DRESSING FOAM HEAVY EXUDATE**, dressing foam heavy exudate 10 cm x 23 cm dressing, 50 (*Mesorb 677401*)
- 12807C **DRESSING FOAM HEAVY EXUDATE**, dressing foam heavy exudate 12.5 cm x 12.5 cm dressing, 10 (*Mextra Superabsorbent 610000*)
- 12788C **DRESSING FOAM HEAVY EXUDATE**, dressing foam heavy exudate 17.5 cm x 22.5 cm dressing, 10 (*Mextra Superabsorbent 610300*)
- 12783T **DRESSING FOAM HEAVY EXUDATE**, dressing foam heavy exudate 22.5 cm x 32.5 cm dressing, 10 (*Mextra Superabsorbent 610500*)
- 12781Q **DRESSING FOAM HEAVY EXUDATE**, dressing foam heavy exudate 23 cm x 25 cm dressing, 30 (*Mesorb 677701*)

Deletion – Brand

- 10598T *Parapane Osteo, AF* – **PARACETAMOL**, paracetamol 665 mg modified release tablet, 96

Advance Notices**1 March 2022****Deletion – Brand**

- 4591P *Gabapentin Aspen 100, RW* – **GABAPENTIN**, gabapentin 100 mg capsule, 100
- 4592Q *Gabapentin Aspen 300, RW* – **GABAPENTIN**, gabapentin 300 mg capsule, 100
- 4593R *Gabapentin Aspen 400, RW* – **GABAPENTIN**, gabapentin 400 mg capsule, 100
- 4594T *Gabapentin Aspen 600, RW* – **GABAPENTIN**, gabapentin 600 mg tablet, 100
- 4595W *Gabapentin Aspen 800, RW* – **GABAPENTIN**, gabapentin 800 mg tablet, 100

General Pharmaceutical Benefits

▪ ACALABRUTINIB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note For the purposes of administering this restriction, current Bruton tyrosine kinase inhibitors are: acalabrutinib, ibrutinib.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Mantle cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton tyrosine kinase inhibitor therapy; OR
- Patient must have developed intolerance to another Bruton tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

Authority required

Mantle cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

Authority required

Mantle cell lymphoma

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Clinical criteria:

- Patient must have received treatment with this drug prior to 1 February 2022, **AND**
- The condition must have relapsed or be refractory to at least one prior therapy prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a WHO performance status of 0 or 1 at the time non-PBS-subsidised treatment with this drug for this condition was initiated, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have been untreated with Bruton tyrosine kinase inhibitor therapy at treatment initiation with this drug; OR
- Patient must have developed intolerance to another Bruton tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

acalabrutinib 100 mg capsule, 56

12826C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	8218.96	42.50	Calquence [AP]

▪ DUPILUMAB

Note Instructions on the use of the Eczema Area and Severity Index and copyright details can be found here: <https://www.dupixent.co.uk/-/media/EMS/Conditions/Dermatology/Brands/Dupixent-UK/global/1051-EASI-Leaflet-v6-webready.pdf>

Note Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here: <https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index>

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment of the whole body

Clinical criteria:

- Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this PBS indication.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

Population criteria:

- Patient must be 12 years of age or older.

State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.

Note Instructions on the use of the Physician's Global Assessment (5-point scale) can be obtained from Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment of the whole body

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the whole body, **AND**
- Patient must have achieved an adequate response within the first 16 weeks of treatment; OR
- Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

For the purposes of this restriction, an adequate response to treatment is defined as:

(a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and

(b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

State each of the current EASI and DLQI scores for this authority application.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment of the face and/or hands

Clinical criteria:

- The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; OR
- The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this PBS indication.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

Population criteria:

- Patient must be 12 years of age or older.

State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for:

- erythema,
- oedema/papulation,
- excoriation,
- lichenification

Acceptable scores can be:

- current scores; or
- past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores.

The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment of the face and/or hands

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the face/hands, **AND**
- Patient must have achieved an adequate response within the first 16 weeks of treatment; OR
- Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as:

- (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or
- (ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and
- (b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - treatment of the whole body (Grandfather listing)

Clinical criteria:

- Patient must have been receiving treatment with this biological medicine for this PBS indication prior to 1 March 2021, **AND**

- Patient must have had a Physicians Global Assessment (PGA) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days prior to commencing non-PBS-subsidised therapy with this biological medicine, **AND**
- Patient must have had an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days prior to commencing non-PBS-subsidised therapy with this biological medicine, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to having commenced non-PBS-subsidised therapy with this biological medicine; OR
- Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised therapy with this biological medicine, **AND**
- Patient must not be experiencing an inadequate response to current non-PBS-subsidised therapy with this biological medicine, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this PBS indication, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this indication, prior to commencing non-PBS-subsidised therapy with this biological medicine.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

Population criteria:

- Patient must be 12 years of age or older.

State each of the qualifying PGA, EASI and DLQI scores in the authority application. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine must be documented in the patient's medical records.

The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Instructions on the use of the Physician's Global Assessment (5-point scale) can be obtained from Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - treatment of the face and/or hands (Grandfather listing)

Clinical criteria:

- Patient must have been receiving treatment with this biological medicine for this PBS indication prior to 1 March 2021, **AND**
- The condition must have had at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised therapy with this biological medicine; OR
- The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised therapy with this biological medicine, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to having commenced non-PBS-subsidised therapy with this biological medicine; OR
- Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised therapy with this biological medicine, **AND**
- Patient must not be experiencing an inadequate response to current non-PBS-subsidised therapy with this biological medicine, **AND**
- The treatment must be the sole PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have experienced an inadequate response to this biological medicine in this indication, prior to commencing non-PBS-subsidised therapy with this biological medicine.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

Population criteria:

- Patient must be 12 years of age or older.

State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings for erythema, oedema/papulation, excoriation, lichenification that were present prior to having commenced non-PBS-subsidised therapy, in the authority

application. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine is/are to be documented in the patient's medical records.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

12292Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1754.28	42.50	Dupilumab [SW]

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

12291X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1754.28	42.50	Dupilumab [SW]

■ IBRUTINIB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note For the purposes of administering this restriction, current Bruton tyrosine kinase inhibitors are: acalabrutinib, ibrutinib.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Mantle cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have relapsed or be refractory to at least one prior therapy, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must be untreated with Bruton tyrosine kinase inhibitor therapy; OR
- Patient must have developed intolerance to another Bruton tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal, when treated for this PBS indication.

Authority required

Mantle cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

ibrutinib 140 mg capsule, 120

11419B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	11672.27	42.50	Imbruvica [JC]

■ LEVOTHYROXINE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

levothyroxine sodium 125 microgram tablet, 200

12830G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	25.51	26.81	Eltroxin [LT]

NP

■ LEVOTHYROXINE

Note Eltroxin is not interchangeable with Oroxine, Eutroxsig or Levoxine on a dose to dose basis, and dose titration may be required.

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

levothyroxine sodium 50 microgram tablet, 200

2174K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	23.13	24.43	Eltroxin [LT]	
			^B 1.44	24.57	24.43	^a Eutroxsig [LN]	^a LEVOXINE [RA]
						^a Oroxine [AS]	

NP

levothyroxine sodium 75 microgram tablet, 200

9287T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	23.55	24.85	Eltroxin [LT]	
						^a Eutroxsig [LN]	^a LEVOXINE [RA]
			^B 1.49	25.04	24.85	^a Oroxine [AS]	

levothyroxine sodium 200 microgram tablet, 200

2173J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	25.51	26.81	Eltroxin [LT]	
						^a Eutroxsig [LN]	^a LEVOXINE [RA]
			^B 1.44	26.95	26.81	^a Oroxine [AS]	

levothyroxine sodium 100 microgram tablet, 200

2175L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	1	1	..	23.53	24.83	Eltroxin [LT]	
						^a Eutroxsig [LN]	^a LEVOXINE [RA]
			^B 1.44	24.97	24.83	^a Oroxine [AS]	

■ UPADACITINIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Dose change (increasing up to the 30 mg dose, or, decreasing back down to the 15 mg dose) - whole body, or, face/hands

Treatment criteria:

- Patient must not be undergoing each of: (i) commencing treatment through this treatment phase listing, (ii) treatment accessed through this treatment phase on more than 2 consecutive occasions, **AND**
- Patient must be undergoing existing PBS-subsidised treatment with this therapy where each of the following is true: (i) there is a change in daily dose, (ii) any remaining PBS repeat prescriptions for the strength that the patient is changing from, is marked as 'cancelled', **AND**
- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

upadacitinib 30 mg modified release tablet, 28

12827D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	2076.38	42.50	Rinvoq [VE]

upadacitinib 15 mg modified release tablet, 28

12835M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1271.40	42.50	Rinvoq [VE]

■ UPADACITINIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications:

Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). **British Journal of Dermatology** 2014 December;171(6):1318-25.

Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. **The Journal of Allergy and Clinical Immunology** 2014 October;134(4):800-7

Note Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here: <https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index>

Note The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication:

Fatamura M et al. **Journal of the American Academy of Dermatology** 2016; 64(2): 288-94

The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.

Note Dose changes subsequent to this authority application, whether they occur during an initial treatment or continuing treatment phase, may occur under the 'Dose change' treatment phase listing.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment with this drug of the whole body

Clinical criteria:

- Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 day, **AND**
- Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- Patient must not have experienced an inadequate response to this therapy.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

Population criteria:

- Patient must be 12 years of age or older.

State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Initial treatment with this drug of the face and/or hands

Clinical criteria:

- The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; OR
- The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, **AND**
- Patient must not have experienced an inadequate response to this therapy.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

Population criteria:

- Patient must be 12 years of age or older.

State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for:

(i) erythema,

(ii) oedema/papulation,

(iii) excoriation,

(iv) lichenification

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores.

The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.

upadacitinib 30 mg modified release tablet, 28

12836N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	2076.38	42.50	Rinvoq [VE]

upadacitinib 15 mg modified release tablet, 28

12828E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	4	..	1271.40	42.50	Rinvoq [VE]

■ UPADACITINIB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications:

Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). **British Journal of Dermatology** 2014 December;171(6):1318-25.

Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. **The Journal of Allergy and Clinical Immunology** 2014 October;134(4):800-7

Note Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here:

<https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index>

Note The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication:

Fatumura M et al. **Journal of the American Academy of Dermatology** 2016; 64(2): 288-94

The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.

Note Dose changes subsequent to this authority application, whether they occur during an initial treatment or continuing treatment phase, may occur under the 'Dose change' treatment phase listing.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply (treatment of the whole body) - Grandfather arrangements

Clinical criteria:

- Patient must have been receiving treatment with this therapy for chronic severe atopic dermatitis prior to 1 February 2022, **AND**
- Patient must have had a Physicians Global Assessment (PGA) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days prior to commencing non-PBS-subsidised treatment with this therapy, **AND**
- Patient must have had an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days prior to having commenced non-PBS-subsidised treatment with this therapy, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to having commenced non-PBS-subsidised treatment with this therapy; OR
- Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised treatment with this therapy, **AND**
- Patient must not be experiencing an inadequate response to non-PBS-subsidised treatment with this therapy, **AND**
- Patient must not have experienced an inadequate response to this therapy in this indication, prior to commencing non-PBS-subsidised treatment with this therapy.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

Population criteria:

- Patient must be 12 years of age or older.
- State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application.

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply (treatment of the face and/or hands) - Grandfather arrangements

Clinical criteria:

- Patient must have been receiving treatment with this therapy for chronic severe atopic dermatitis prior to 1 February 2022, **AND**
- The condition must have had at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised treatment with this therapy; **OR**
- The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised treatment with this therapy, **AND**
- Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to having commenced non-PBS-subsidised treatment with this therapy; **OR**
- Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured, **AND**
- The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised treatment with this therapy, **AND**
- Patient must not be experiencing an inadequate response to non-PBS-subsidised treatment with this therapy, **AND**
- Patient must not have experienced an inadequate response to this therapy in this indication, prior to commencing non-PBS-subsidised treatment with this therapy.

Treatment criteria:

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

Population criteria:

- Patient must be 12 years of age or older.

State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for:

(i) erythema,

(ii) oedema/papulation,

(iii) excoriation,

(iv) lichenification

Acceptable scores can be:

(a) current scores; or

(b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication.

State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores.

The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.

A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only.

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment with this drug of the whole body

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the whole body, **AND**
- Patient must have achieved an adequate response prior to this first continuing treatment authority application; OR
- Patient must have maintained an adequate response to their most recent supply of this therapy for this PBS indication if this is any Continuing treatment authority application other than the first; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

For the purposes of this restriction, an adequate response to treatment is defined as:

(a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and

(b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

State each of the current EASI and DLQI scores for this authority application.

Authority required

Chronic severe atopic dermatitis

Treatment Phase: Continuing or resuming treatment with this drug of the face and/or hands

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this therapy for the treatment of chronic severe atopic dermatitis affecting the face/hands, **AND**
- Patient must have achieved an adequate response prior to this first continuing treatment authority application; OR
- Patient must have maintained an adequate response to their most recent supply of this therapy for this PBS indication if this is any Continuing treatment authority application other than the first; OR
- Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application.

Treatment criteria:

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist, **AND**
- Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).

For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as:

(a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or

(ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and

(b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline

Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above.

Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes

upadacitinib 30 mg modified release tablet, 28

12829F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2076.38	42.50	Rinvoq [VE]

upadacitinib 15 mg modified release tablet, 28

12831H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1271.40	42.50	Rinvoq [VE]

Highly Specialised Drugs Program (Private Hospital)

▪ PEGFILGRASTIM

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Pelgraz or Ziextenzo is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Authority required (STREAMLINED)

9235

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

9303

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

6363X	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	368.03	^a Neulasta [JU]	^a Pelgraz [OC]
					^a Ristempa [JO]	^a Tezmota [JX]
					^a Ziextenzo [SZ]	

Highly Specialised Drugs Program (Public Hospital)

▪ PEGFILGRASTIM

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Pelgraz or Ziextenzo is encouraged for treatment naive patients.

Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).

Authority required (STREAMLINED)

7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority required (STREAMLINED)

7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

9514R	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	346.39	^a Neulasta [JU]	^a Pelgraz [OC]
					^a Ristempa [JO]	^a Tezmota [JX]
					^a Ziextenzo [SZ]	

Repatriation Pharmaceutical Benefits Scheme

▪ DRESSING NON-ADHERENT ABSORBENT

dressings non-adherent absorbent 10 cm x 23 cm dressing, 50

12825B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	77.13	6.80	Mesorb 677401 [MH]

dressings non-adherent absorbent 10 cm x 13 cm dressing, 50

12832J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	56.70	6.80	Mesorb 677001 [MH]

dressings non-adherent absorbent 23 cm x 25 cm dressing, 30

12824Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	100.14	6.80	Mesorb 677701 [MH]

dressings non-adherent absorbent 22.5 cm x 32.5 cm hydroactive dressing, 10

12833K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	89.49	6.80	Mextra Superabsorbent 610500 [MH]

dressings non-adherent absorbent 17.5 cm x 22.5 cm hydroactive dressing, 10

12834L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	51.86	6.80	Mextra Superabsorbent 610300 [MH]

dressings non-adherent absorbent 12.5 cm x 12.5 cm hydroactive dressing, 10

12837P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	32.83	6.80	Mextra Superabsorbent 610000 [MH]