Australian Government
Department of Health and Aged Care

PBS

Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 May 2024

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 May 2024 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	$8.37
	Dangerous drug fee	$5.18
	Extemporaneously-prepared	$10.41
	Allowable additional patient charge*	$3.45
Additional Fees (for safety net prices):	Ready-prepared	$1.40
	Extemporaneously-prepared	$1.80
Patient Co-payments:	General	$31.60
	Concessional	$7.70
Safety Net Thresholds:	General	$1647.90
	Concessional	$277.20
Safety Net Card Issue Fee:		$12.04

* 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 May 2024. 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

13625D **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack *(GlucaGen Hypokit (Germany))*

3485K **PROCAINE BENZYLPENICILLIN**, procaine benzylpenicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes *(Cilicaine)*

Deletion – Equivalence Indicator

3467L *GlucaGen Hypokit, NO* – **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

Deletion – Note

3467L **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack *(GlucaGen Hypokit)*

Advance Notices

1 July 2024

Deletion – Brand

12108G *Asmol CFC-Free with dose counter, AF* – **SALBUTAMOL**, salbutamol 100 microgram/actuation inhalation, 200 actuations

12108G *Zempreon CFC-Free with dose counter, AL* – **SALBUTAMOL**, salbutamol 100 microgram/actuation inhalation, 200 actuations

General Pharmaceutical Benefits

Additions

Addition – Item

14116Y **ABEMACICLIB**, abemaciclib 50 mg tablet, 56 *(Verzenio)*

14105J **ABEMACICLIB**, abemaciclib 100 mg tablet, 56 *(Verzenio)*

14134X **ABEMACICLIB**, abemaciclib 150 mg tablet, 56 *(Verzenio)*

14118C **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE, ISOLEUCINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID**, amino acid formula with vitamins and minerals without valine, leucine, isoleucine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets *(MSUD explore5)*

14114W **AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT METHIONINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID**, amino acid formula with vitamins and minerals, without methionine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets *(HCU explore5)*

14126L **AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT PHENYLALANINE, TYROSINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID**, amino acid formula with vitamins and minerals, without phenylalanine, tyrosine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets *(TYR explore5)*

14132T **COLESTYRAMINE**, colestyramine 4 g powder for oral liquid, 60 pouches *(Cholestyramine (Ascend, USA))*

14145L **COLESTYRAMINE**, colestyramine 4 g powder for oral liquid, 60 pouches *(Cholestyramine (Ascend, USA))*

14123H **MAVACAMTEN**, mavacamten 2.5 mg capsule, 28 *(Camzyos)*

14135Y **MAVACAMTEN**, mavacamten 2.5 mg capsule, 28 *(Camzyos)*

14113T **MAVACAMTEN**, mavacamten 5 mg capsule, 28 *(Camzyos)*

14117B **MAVACAMTEN**, mavacamten 5 mg capsule, 28 *(Camzyos)*

14137C **MAVACAMTEN**, mavacamten 10 mg capsule, 28 *(Camzyos)*

14138D **MAVACAMTEN**, mavacamten 10 mg capsule, 28 *(Camzyos)*

14124J **MAVACAMTEN**, mavacamten 15 mg capsule, 28 *(Camzyos)*

14139E **MAVACAMTEN**, mavacamten 15 mg capsule, 28 *(Camzyos)*

14108M **PROCHLORPERAZINE**, prochlorperazine maleate 5 mg tablet, 250 *(Stemetil (Ireland))*

14129P **PROCHLORPERAZINE**, prochlorperazine maleate 5 mg tablet, 250 *(Stemetil (Ireland))*

14111Q **RISANKIZUMAB**, risankizumab 150 mg/mL injection, 1 mL pen device *(Skyrizi)*

14142H **RISANKIZUMAB**, risankizumab 150 mg/mL injection, 1 mL pen device *(Skyrizi)*

14100D **TAFAMIDIS**, tafamidis 61 mg capsule, 30 *(Vyndamax)*

14125K **UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 *(Rinvoq)*

Addition – Brand

9318K *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 75 mg capsule, 10

9320M *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 75 mg capsule, 60

9322P *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 75 mg capsule, 10

13523R *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 110 mg capsule, 60

2753X *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 110 mg capsule, 60

9319L *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 110 mg capsule, 10

9321N *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 110 mg capsule, 60

9323Q *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 110 mg capsule, 10

13489Y *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 150 mg capsule, 60

2769R *PHARMACOR DABIGATRAN, CR* – **DABIGATRAN**, dabigatran etexilate 150 mg capsule, 60

13412X *ARX-LERCANIDIPINE, TX* – **LERCANIDIPINE**, lercanidipine hydrochloride 20 mg tablet, 28

8679T *ARX-LERCANIDIPINE, TX* – **LERCANIDIPINE**, lercanidipine hydrochloride 20 mg tablet, 28

2272N *Chexate, OX* – **METHOTREXATE**, methotrexate 10 mg tablet, 15

8144P *Sumagraine Migraine Relief, GQ* – **SUMATRIPTAN**, sumatriptan 50 mg tablet, 2

13907Y *Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 500 microgram modified release capsule, 30

5299X *Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 500 microgram modified release capsule, 30

13962W *Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 1 mg modified release capsule, 60

5300Y *Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 1 mg modified release capsule, 60

11914C *Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 3 mg modified release capsule, 50

13996P *Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 3 mg modified release capsule, 50

14039X *Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 5 mg modified release capsule, 30

5451X *Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 5 mg modified release capsule, 30

14093R *Teriparatide Lupin, GQ* – **TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL pen device

14017R *APO-Sodium Valproate, TX* – **VALPROATE**, valproate sodium 200 mg enteric tablet, 100

2289L *APO-Sodium Valproate, TX* – **VALPROATE**, valproate sodium 200 mg enteric tablet, 100

13917L *APO-Sodium Valproate, TX* – **VALPROATE**, valproate sodium 500 mg enteric tablet, 100

2290M *APO-Sodium Valproate, TX* – **VALPROATE**, valproate sodium 500 mg enteric tablet, 100

Addition – Equivalence Indicator

9318K *Pradaxa, BY* – **DABIGATRAN**, dabigatran etexilate 75 mg capsule, 10

9322P *Pradaxa, BY* – **DABIGATRAN**, dabigatran etexilate 75 mg capsule, 10

9319L *Pradaxa, BY* – **DABIGATRAN**, dabigatran etexilate 110 mg capsule, 10

9323Q *Pradaxa, BY* – **DABIGATRAN**, dabigatran etexilate 110 mg capsule, 10

2272N *Methoblastin, PF* – **METHOTREXATE**, methotrexate 10 mg tablet, 15

13907Y *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 500 microgram modified release capsule, 30

5299X *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 500 microgram modified release capsule, 30

13962W *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 1 mg modified release capsule, 60

5300Y *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 1 mg modified release capsule, 60

11914C *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 3 mg modified release capsule, 50

13996P *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 3 mg modified release capsule, 50

14039X *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 5 mg modified release capsule, 30

5451X *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 5 mg modified release capsule, 30

Addition – Note

2893G **PROCHLORPERAZINE**, prochlorperazine maleate 5 mg tablet, 25 *(APO-Prochlorperazine, ProCalm, Prochlorperazine GH, Stemetil)*

5205Y **PROCHLORPERAZINE**, prochlorperazine maleate 5 mg tablet, 25 *(APO-Prochlorperazine, ProCalm, Prochlorperazine GH, Stemetil)*

Deletions

Deletion – Item

5484P **AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT LYSINE AND LOW IN TRYPTOPHAN**, amino acid formula with vitamins and minerals without lysine and low in tryptophan powder for oral liquid, 30 x 25 g sachets *(GA express 15)*

13278W **CEFALEXIN**, cefalexin 250 mg/5 mL powder for oral liquid, 100 mL *(Keforal)*

13285F **CEFALEXIN**, cefalexin 250 mg/5 mL powder for oral liquid, 100 mL *(Keforal)*

11191B **CEFUROXIME**, cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL *(Zinnat)*

11192C **CEFUROXIME**, cefuroxime 125 mg/5 mL powder for oral liquid, 100 mL *(Zinnat)*

13612K **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack *(GlucaGen Hypokit (Germany))*

13614M **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack *(GlucaGen Hypokit (Germany))*

13279X **MINOXIDIL**, minoxidil 10 mg tablet, 60 *(Minoxidil 10 mg (Roma Pharmaceuticals))*

1794K **PROCAINE BENZYLPENICILLIN**, procaine benzylpenicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes *(Cilicaine)*

3371K **PROCAINE BENZYLPENICILLIN**, procaine benzylpenicillin 1.5 g/3.4 mL injection, 5 x 3.4 mL syringes *(Cilicaine)*

Deletion – Brand

13532F *Norvapine, ED* – **AMLODIPINE**, amlodipine 5 mg tablet, 30

2751T *Norvapine, ED* – **AMLODIPINE**, amlodipine 5 mg tablet, 30

13562T *Norvapine, ED* – **AMLODIPINE**, amlodipine 10 mg tablet, 30

2752W *Norvapine, ED* – **AMLODIPINE**, amlodipine 10 mg tablet, 30

13179P *Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals), QY* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20

13179P *Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs), QZ* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20

13190F *Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals), QY* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20

13190F *Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs), QZ* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20

13194K *Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Aurobindo – Pro Pharmaceuticals), QY* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20

13194K *Amoxicillin and clavulanate potassium tablets, USP 875 mg/125 mg (Micro Labs), QZ* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 20

3172Y *Risperidone generichealth, GQ* – **RISPERIDONE**, risperidone 4 mg tablet, 60

11296M *Tenofovir Disoproxil Emtricitabine Mylan 300/200, AF* – **TENOFOVIR DISOPROXIL + EMTRICITABINE**, tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30

13969F *Topamax, JC* – **TOPIRAMATE**, topiramate 25 mg tablet, 60

8163P *Topamax, JC* – **TOPIRAMATE**, topiramate 25 mg tablet, 60

13913G *Topamax, JC* – **TOPIRAMATE**, topiramate 50 mg tablet, 60

8164Q *Topamax, JC* – **TOPIRAMATE**, topiramate 50 mg tablet, 60

14008G *Topamax, JC* – **TOPIRAMATE**, topiramate 100 mg tablet, 60

8165R *Topamax, JC* – **TOPIRAMATE**, topiramate 100 mg tablet, 60

14009H *Topamax, JC* – **TOPIRAMATE**, topiramate 200 mg tablet, 60

8166T *Topamax, JC* – **TOPIRAMATE**, topiramate 200 mg tablet, 60

10785P *Trimethoprim Mylan, AL* – **TRIMETHOPRIM**, trimethoprim 300 mg tablet, 7

2666H *Trimethoprim Mylan, AL* – **TRIMETHOPRIM**, trimethoprim 300 mg tablet, 7

2922T *Trimethoprim Mylan, AL* – **TRIMETHOPRIM**, trimethoprim 300 mg tablet, 7

Deletion – Equivalence Indicator

1449G *GlucaGen Hypokit, NO* – **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

5105Q *GlucaGen Hypokit, NO* – **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

2313R *Loniten, PF* – **MINOXIDIL**, minoxidil 10 mg tablet, 100

Deletion – Note

3095X **CEFALEXIN**, cefalexin 250 mg/5 mL powder for oral liquid, 100 mL *(Cefalexin Sandoz, Ibilex 250, Keflex)*

3320R **CEFALEXIN**, cefalexin 250 mg/5 mL powder for oral liquid, 100 mL *(Cefalexin Sandoz, Ibilex 250, Keflex)*

13202W **DARATUMUMAB**, daratumumab 1.8 g/15 mL injection, 15 mL vial *(Darzalex SC)*

13177M **FARICIMAB**, faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial *(Vabysmo)*

13183W **FARICIMAB**, faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial *(Vabysmo)*

1449G **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack *(GlucaGen Hypokit)*

5105Q **GLUCAGON HYDROCHLORIDE**, glucagon hydrochloride 1 mg injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack *(GlucaGen Hypokit)*

2313R **MINOXIDIL**, minoxidil 10 mg tablet, 100 *(Loniten)*

13171F **TEPOTINIB**, tepotinib 225 mg tablet, 60 *(Tepmetko)*

13181R **VERICIGUAT**, vericiguat 2.5 mg tablet, 28 *(Verquvo)*

13186B **VERICIGUAT**, vericiguat 5 mg tablet, 28 *(Verquvo)*

13193J **VERICIGUAT**, vericiguat 10 mg tablet, 28 *(Verquvo)*

Deletion – Restriction

13202W **DARATUMUMAB**, daratumumab 1.8 g/15 mL injection, 15 mL vial *(Darzalex SC)*

13177M **FARICIMAB**, faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial *(Vabysmo)*

13183W **FARICIMAB**, faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial *(Vabysmo)*

13171F **TEPOTINIB**, tepotinib 225 mg tablet, 60 *(Tepmetko)*

13181R **VERICIGUAT**, vericiguat 2.5 mg tablet, 28 *(Verquvo)*

13186B **VERICIGUAT**, vericiguat 5 mg tablet, 28 *(Verquvo)*

13193J **VERICIGUAT**, vericiguat 10 mg tablet, 28 *(Verquvo)*

Alterations

Alteration – Note

11876C **ABEMACICLIB**, abemaciclib 50 mg tablet, 56 *(Verzenio)*

11871T **ABEMACICLIB**, abemaciclib 100 mg tablet, 56 *(Verzenio)*

11868P **ABEMACICLIB**, abemaciclib 150 mg tablet, 56 *(Verzenio)*

12818P **PALBOCICLIB**, palbociclib 75 mg tablet, 21 *(Ibrance)*

12819Q **PALBOCICLIB**, palbociclib 100 mg tablet, 21 *(Ibrance)*

12822W **PALBOCICLIB**, palbociclib 125 mg tablet, 21 *(Ibrance)*

13864Q **PERAMPANEL**, perampanel 4 mg tablet, 28 *(Fycompa)*

14046G **PERAMPANEL**, perampanel 6 mg tablet, 28 *(Fycompa)*

11385F **RIBOCICLIB**, ribociclib 200 mg tablet, 21 *(Kisqali)*

11386G **RIBOCICLIB**, ribociclib 200 mg tablet, 63 *(Kisqali)*

11397W **RIBOCICLIB**, ribociclib 200 mg tablet, 42 *(Kisqali)*

Alteration – Restriction

11876C **ABEMACICLIB**, abemaciclib 50 mg tablet, 56 *(Verzenio)*

11871T **ABEMACICLIB**, abemaciclib 100 mg tablet, 56 *(Verzenio)*

11868P **ABEMACICLIB**, abemaciclib 150 mg tablet, 56 *(Verzenio)*

12607M **ALIROCUMAB**, alirocumab 75 mg/mL injection, 2 x 1 mL pen devices *(Praluent)*

12608N **ALIROCUMAB**, alirocumab 150 mg/mL injection, 2 x 1 mL pen devices *(Praluent)*

11985T **EVOLOCUMAB**, evolocumab 140 mg/mL injection, 1 mL pen device *(Repatha)*

11986W **EVOLOCUMAB**, evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge *(Repatha)*

13079J **NIRAPARIB**, niraparib 100 mg capsule, 84 *(Zejula)*

13089X **NIRAPARIB**, niraparib 100 mg capsule, 56 *(Zejula)*

14088L **NIRAPARIB**, niraparib 100 mg capsule, 56 *(Zejula)*

14094T **NIRAPARIB**, niraparib 100 mg capsule, 56 *(Zejula)*

8233H **ONDANSETRON**, ondansetron 4 mg/5 mL oral liquid, 50 mL *(Zofran syrup 50 mL)*

1594X **ONDANSETRON**, ondansetron 4 mg tablet, 10 *(APO-Ondansetron, APX-Ondansetron, Ondansetron Mylan Tablets, Ondansetron SZ, Ondansetron-DRLA, Zofran, Zotren 4)*

5472B **ONDANSETRON**, ondansetron 4 mg orally disintegrating tablet, 10 *(APX-Ondansetron ODT, Ondansetron Mylan ODT, Ondansetron ODT Lupin, Ondansetron ODT-DRLA, Ondansetron SZ ODT, Zotren ODT)*

1595Y **ONDANSETRON**, ondansetron 8 mg tablet, 10 *(APO-Ondansetron, APX-Ondansetron, Ondansetron Mylan Tablets, Ondansetron SZ, Ondansetron-DRLA, Zofran, Zotren 8)*

5473C **ONDANSETRON**, ondansetron 8 mg orally disintegrating tablet, 10 *(APX-Ondansetron ODT, Ondansetron Mylan ODT, Ondansetron ODT Lupin, Ondansetron ODT-DRLA, Ondansetron SZ ODT, Zotren ODT)*

8412R **ONDANSETRON**, ondansetron 4 mg wafer, 10 *(Zofran Zydis)*

8413T	**ONDANSETRON**, ondansetron 8 mg wafer, 10 *(Zofran Zydis)*
12818P	**PALBOCICLIB**, palbociclib 75 mg tablet, 21 *(Ibrance)*
12819Q	**PALBOCICLIB**, palbociclib 100 mg tablet, 21 *(Ibrance)*
12822W	**PALBOCICLIB**, palbociclib 125 mg tablet, 21 *(Ibrance)*
11385F	**RIBOCICLIB**, ribociclib 200 mg tablet, 21 *(Kisqali)*
11386G	**RIBOCICLIB**, ribociclib 200 mg tablet, 63 *(Kisqali)*
11397W	**RIBOCICLIB**, ribociclib 200 mg tablet, 42 *(Kisqali)*
11979L	**UPADACITINIB**, upadacitinib 15 mg modified release tablet, 28 *(Rinvoq)*

Alteration – Manufacturer Code

		From	*To*
2122Q	*Ordine 2* – **MORPHINE**, morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL	MF	XT
5237P	*Ordine 2* – **MORPHINE**, morphine hydrochloride trihydrate 2 mg/mL oral liquid, 200 mL	MF	XT
2123R	*Ordine 5* – **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL	MF	XT
5238Q	*Ordine 5* – **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL	MF	XT
2124T	*Ordine 10* – **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL	MF	XT
5239R	*Ordine 10* – **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL	MF	XT

Alteration – Number of Repeats

		From	*To*
14087K	**INCLISIRAN**, inclisiran 284 mg/1.5 mL injection, 1.5 mL syringe *(Leqvio)*	1	0
13864Q	**PERAMPANEL**, perampanel 4 mg tablet, 28 *(Fycompa)*	2	5
14046G	**PERAMPANEL**, perampanel 6 mg tablet, 28 *(Fycompa)*	2	5

Supply Only

When a product is deleted from the Schedule it may be available under Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted. Substitution of Supply Only items/brands with products flagged as “equivalent for substitution” still apply as specified in the Schedule at the time the script was written.
Further information on Supply Only arrangements is available at https://www.pbs.gov.au/browse/medicine-listing/supply-only
Supply Only Commencing 1 May 2024

8361C	**CAPECITABINE**, capecitabine 150 mg tablet, 60 *(Capecitabine-DRLA)*
5502N	**CARBOMER-974P**, carbomer-974P 0.3% eye gel, 30 x 500 mg ampoules *(Poly Gel)*
8514D	**CARBOMER-974P**, carbomer-974P 0.3% eye gel, 30 x 500 mg ampoules *(Poly Gel)*
5521N	**DEXTRAN-70 + HYPROMELLOSE**, dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL ampoules *(Bion Tears)*
8299T	**DEXTRAN-70 + HYPROMELLOSE**, dextran-70 0.1% + hypromellose 0.3% eye drops, 28 x 0.4 mL ampoules *(Bion Tears)*
1438Q	**FLUOROMETHOLONE ACETATE**, fluorometholone acetate 0.1% eye drops, 5 mL *(Flarex)*
5533F	**FLUOROMETHOLONE ACETATE**, fluorometholone acetate 0.1% eye drops, 5 mL *(Flarex)*
11827L	**RISANKIZUMAB**, risankizumab 75 mg/0.83 mL injection, 2 x 0.83 mL syringes *(Skyrizi)*
11858D	**RISANKIZUMAB**, risankizumab 75 mg/0.83 mL injection, 2 x 0.83 mL syringes *(Skyrizi)*

Advance Notices

1 June 2024

Deletion – Brand

13858J	*Arimidex, AP* – **ANASTROZOLE**, anastrozole 1 mg tablet, 30
8179L	*Arimidex, AP* – **ANASTROZOLE**, anastrozole 1 mg tablet, 30
1263L	*Bisalax, OX* – **BISACODYL**, bisacodyl 10 mg/5 mL enema, 25 x 5 mL

12114N *Ceftriaxone Alphapharm, AF* – **CEFTRIAXONE**, ceftriaxone 1 g injection, 10 vials

1788D *Ceftriaxone Alphapharm, AF* – **CEFTRIAXONE**, ceftriaxone 1 g injection, 5 vials

1357K *Dosulepin Mylan, AL* – **DOSULEPIN (DOTHIEPIN)**, dosulepin (dothiepin) hydrochloride 25 mg capsule, 50

13369P *Enalapril generichealth, GQ* – **ENALAPRIL**, enalapril maleate 5 mg tablet, 30

13465Q *Enalapril generichealth, GQ* – **ENALAPRIL**, enalapril maleate 10 mg tablet, 30

1368B *Enalapril generichealth, GQ* – **ENALAPRIL**, enalapril maleate 10 mg tablet, 30

1370D *Enalapril generichealth, GQ* – **ENALAPRIL**, enalapril maleate 5 mg tablet, 30

9024Y *Nizoral 2% Cream, JT* – **KETOCONAZOLE**, ketoconazole 2% cream, 30 g

14000W *Noumed Mycophenolate, VO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

8650G *Noumed Mycophenolate, VO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

13441K *Nebivolol Viatris, AL* – **NEBIVOLOL**, nebivolol 10 mg tablet, 28

13568D *Nebivolol Viatris, AL* – **NEBIVOLOL**, nebivolol 1.25 mg tablet, 28

9312D *Nebivolol Viatris, AL* – **NEBIVOLOL**, nebivolol 10 mg tablet, 28

9316H *Nebivolol Viatris, AL* – **NEBIVOLOL**, nebivolol 1.25 mg tablet, 28

13921Q *NOUMED PIOGLITAZONE, VO* – **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28

13921Q *Pioglitazone Sandoz, SZ* – **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28

14057W *NOUMED PIOGLITAZONE, VO* – **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28

14057W *Pioglitazone Sandoz, SZ* – **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28

8695P *NOUMED PIOGLITAZONE, VO* – **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28

8695P *Pioglitazone Sandoz, SZ* – **PIOGLITAZONE**, pioglitazone 30 mg tablet, 28

8696Q *NOUMED PIOGLITAZONE, VO* – **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28

8696Q *Pioglitazone Sandoz, SZ* – **PIOGLITAZONE**, pioglitazone 45 mg tablet, 28

13406N *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

13586C *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

13588E *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

13589F *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

2574L *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

2594M *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

2606E *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

2628H *Noumed Rosuvastatin, VO* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

5480K *NOUMED VALACICLOVIR, VO* – **VALACICLOVIR**, valaciclovir 500 mg tablet, 30

8134D *NOUMED VALACICLOVIR, VO* – **VALACICLOVIR**, valaciclovir 500 mg tablet, 30

1 July 2024
Deletion – Brand

12117R *Calquence, AP* – **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56

12826C *Calquence, AP* – **ACALABRUTINIB**, acalabrutinib 100 mg capsule, 56

8717T *Aripic Aripiprazole, LR* – **ARIPIPRAZOLE**, aripiprazole 10 mg tablet, 30

13468W *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

13495G *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30

8213G *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30

8215J *Atorvastatin GH, GQ* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30

13436E *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 8 mg tablet, 30

13438G *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30

13565Y *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30

13592J *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 4 mg tablet, 30

8295N *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 4 mg tablet, 30

8296P *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 8 mg tablet, 30

8297Q *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30

8889W *NOUMED CANDESARTAN, VO* – **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30

11169W *Ceftriaxone Alphapharm, AF* – **CEFTRIAXONE**, ceftriaxone 2 g injection, 5 vials

12112L *Ceftriaxone Alphapharm, AF* – **CEFTRIAXONE**, ceftriaxone 2 g injection, 10 vials

3138E *Clindamycin BNM, BZ* – **CLINDAMYCIN**, clindamycin 150 mg capsule, 24

5057E *Clindamycin BNM, BZ* – **CLINDAMYCIN**, clindamycin 150 mg capsule, 24

3118D *Depo-Ralovera, FZ* – **MEDROXYPROGESTERONE**, medroxyprogesterone acetate 150 mg/mL injection, 1 mL vial

12109H *Asmol CFC-Free with dose counter, AF* – **SALBUTAMOL**, salbutamol 100 microgram/actuation inhalation, 200 actuations

12109H *Zempreon CFC-Free with dose counter, AL* – **SALBUTAMOL**, salbutamol 100 microgram/actuation inhalation, 200 actuations

12670W *Terrosa, FX* – **TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL cartridge

13891D *Terrosa, FX* – **TERIPARATIDE**, teriparatide 250 microgram/mL injection, 2.4 mL cartridge

13913G *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 50 mg tablet, 60

13969F *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 25 mg tablet, 60

14008G *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 100 mg tablet, 60

14009H *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 200 mg tablet, 60

8163P *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 25 mg tablet, 60

8164Q *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 50 mg tablet, 60

8165R *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 100 mg tablet, 60

8166T *NOUMED TOPIRAMATE, VO* – **TOPIRAMATE**, topiramate 200 mg tablet, 60

1 August 2024
Deletion – Brand

8357W *Acamprosate Mylan, AL* – **ACAMPROSATE**, acamprosate calcium 333 mg enteric tablet, 180

13955L *Acarbose Mylan, AF* – **ACARBOSE**, acarbose 50 mg tablet, 90

8188Y *Acarbose Mylan, AF* – **ACARBOSE**, acarbose 50 mg tablet, 90

12115P *Cephazolin Alphapharm, AF* – **CEFAZOLIN**, cefazolin 2 g injection, 10 vials

12118T *Cephazolin Alphapharm, AF* – **CEFAZOLIN**, cefazolin 2 g injection, 10 vials

9159C *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

13884R *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100

14000W *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

8649F *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100

8650G *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

2335X *Cipla Pregabalin, LR* – **PREGABALIN**, pregabalin 75 mg capsule, 56

2348N *Cipla Pregabalin, LR* – **PREGABALIN**, pregabalin 25 mg capsule, 56

2363J *Cipla Pregabalin, LR* – **PREGABALIN**, pregabalin 300 mg capsule, 56

Palliative Care

Alterations

Alteration – Manufacturer Code

		From	*To*
12549L	*Ordine 5* – **MORPHINE**, morphine hydrochloride trihydrate 5 mg/mL oral liquid, 200 mL	MF	XT
12472K	*Ordine 10* – **MORPHINE**, morphine hydrochloride trihydrate 10 mg/mL oral liquid, 200 mL	MF	XT

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

14106K	**DIFELIKEFALIN**, difelikefalin 50 microgram/mL injection, 12 x 1 mL vials *(Korsuva)*
14110P	**DIFELIKEFALIN**, difelikefalin 50 microgram/mL injection, 12 x 1 mL vials *(Korsuva)*
14115X	**ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 *(Revolade)*
14119D	**ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 *(Revolade)*
14136B	**ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 *(Revolade)*
14107L	**ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 *(Revolade)*
14127M	**ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 *(Revolade)*
14143J	**ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 *(Revolade)*

Addition – Brand

9681M	*Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 500 microgram modified release capsule, 30
9682N	*Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 1 mg modified release capsule, 60
11920J	*Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 3 mg modified release capsule, 50
9683P	*Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 5 mg modified release capsule, 30

Addition – Equivalence Indicator

9681M	*ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 500 microgram modified release capsule, 30
9682N	*ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 1 mg modified release capsule, 60
11920J	*ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 3 mg modified release capsule, 50
9683P	*ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 5 mg modified release capsule, 30

Deletions

Deletion – Note

12201E	**AMBRISENTAN**, ambrisentan 5 mg tablet, 30 *(Ambrisentan Mylan, Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris)*
12180C	**AMBRISENTAN**, ambrisentan 10 mg tablet, 30 *(Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris)*
12148J	**BOSENTAN**, bosentan 62.5 mg tablet, 60 *(BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Mylan, Bosentan RBX, Tracleer)*
12146G	**BOSENTAN**, bosentan 125 mg tablet, 60 *(BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan GH, Bosentan Mylan, Bosentan RBX, Tracleer)*
13163T	**BUROSUMAB**, burosumab 10 mg/mL injection, 1 mL vial *(Crysvita)*
13136J	**BUROSUMAB**, burosumab 20 mg/mL injection, 1 mL vial *(Crysvita)*
13154H	**BUROSUMAB**, burosumab 30 mg/mL injection, 1 mL vial *(Crysvita)*
10111E	**EPOPROSTENOL**, epoprostenol 500 microgram injection, 1 vial *(Veletri)*
11069N	**EPOPROSTENOL**, epoprostenol 500 microgram injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack *(Flolan)*
10129D	**EPOPROSTENOL**, epoprostenol 1.5 mg injection, 1 vial *(Veletri)*
11082G	**EPOPROSTENOL**, epoprostenol 1.5 mg injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack *(Flolan)*

6456T **ILOPROST**, iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules *(Ventavis)*

12135Q **MACITENTAN**, macitentan 10 mg tablet, 30 *(Opsumit)*

13197N **PEGCETACOPLAN**, pegcetacoplan 1.08 g/20 mL injection, 20 mL vial *(Empaveli)*

12138W **SILDENAFIL**, sildenafil 20 mg tablet, 90 *(Revatio, SILDATIO PHT, Sildenafil PHT APOTEX, Sildenafil Sandoz PHT 20)*

12150L **TADALAFIL**, tadalafil 20 mg tablet, 56 *(Adcirca, TADALIS 20, Tadalca)*

Deletion – Restriction

12201E **AMBRISENTAN**, ambrisentan 5 mg tablet, 30 *(Ambrisentan Mylan, Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris)*

12180C **AMBRISENTAN**, ambrisentan 10 mg tablet, 30 *(Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris)*

12148J **BOSENTAN**, bosentan 62.5 mg tablet, 60 *(BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Mylan, Bosentan RBX, Tracleer)*

12146G **BOSENTAN**, bosentan 125 mg tablet, 60 *(BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan GH, Bosentan Mylan, Bosentan RBX, Tracleer)*

13163T **BUROSUMAB**, burosumab 10 mg/mL injection, 1 mL vial *(Crysvita)*

13136J **BUROSUMAB**, burosumab 20 mg/mL injection, 1 mL vial *(Crysvita)*

13154H **BUROSUMAB**, burosumab 30 mg/mL injection, 1 mL vial *(Crysvita)*

10111E **EPOPROSTENOL**, epoprostenol 500 microgram injection, 1 vial *(Veletri)*

11069N **EPOPROSTENOL**, epoprostenol 500 microgram injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack *(Flolan)*

10129D **EPOPROSTENOL**, epoprostenol 1.5 mg injection, 1 vial *(Veletri)*

11082G **EPOPROSTENOL**, epoprostenol 1.5 mg injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack *(Flolan)*

6456T **ILOPROST**, iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules *(Ventavis)*

12135Q **MACITENTAN**, macitentan 10 mg tablet, 30 *(Opsumit)*

13197N **PEGCETACOPLAN**, pegcetacoplan 1.08 g/20 mL injection, 20 mL vial *(Empaveli)*

12138W **SILDENAFIL**, sildenafil 20 mg tablet, 90 *(Revatio, SILDATIO PHT, Sildenafil PHT APOTEX, Sildenafil Sandoz PHT 20)*

12150L **TADALAFIL**, tadalafil 20 mg tablet, 56 *(Adcirca, TADALIS 20, Tadalca)*

Advance Notices

1 June 2024

Deletion – Brand

12201E *Ambrisentan Mylan, AF* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30

9648T *Ambrisentan Mylan, AF* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30

12139X *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12143D *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12146G *Tracleer, JC* – **BOSENTAN**, bosentan 125 mg tablet, 60

12148J *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

6429J *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

6430K *Tracleer, JC* – **BOSENTAN**, bosentan 125 mg tablet, 60

6209T *Noumed Mycophenolate, VO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

1 August 2024

Deletion – Brand

12146G *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60

6430K *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60

11888Q *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

9627Q *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

6208R *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100

6209T *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

14140F **DIFELIKEFALIN**, difelikefalin 50 microgram/mL injection, 12 x 1 mL vials *(Korsuva)*

14141G **DIFELIKEFALIN**, difelikefalin 50 microgram/mL injection, 12 x 1 mL vials *(Korsuva)*

14120E **ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 *(Revolade)*

14128N **ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 *(Revolade)*

14144K **ELTROMBOPAG**, eltrombopag 25 mg tablet, 28 *(Revolade)*

14112R **ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 *(Revolade)*

14121F **ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 *(Revolade)*

14131R **ELTROMBOPAG**, eltrombopag 50 mg tablet, 28 *(Revolade)*

Addition – Brand

9664P *Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 500 microgram modified release capsule, 30

9665Q *Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 1 mg modified release capsule, 60

11907Q *Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 3 mg modified release capsule, 50

9666R *Tacrolimus XR Sandoz, SZ* – **TACROLIMUS**, tacrolimus 5 mg modified release capsule, 30

Addition – Equivalence Indicator

9664P *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 500 microgram modified release capsule, 30

9665Q *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 1 mg modified release capsule, 60

11907Q *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 3 mg modified release capsule, 50

9666R *ADVAGRAF XL, LQ* – **TACROLIMUS**, tacrolimus 5 mg modified release capsule, 30

Deletions

Deletion – Note

12212R **AMBRISENTAN**, ambrisentan 5 mg tablet, 30 *(Ambrisentan Mylan, Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris)*

12186J **AMBRISENTAN**, ambrisentan 10 mg tablet, 30 *(Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris)*

12145F **BOSENTAN**, bosentan 62.5 mg tablet, 60 *(BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Mylan, Bosentan RBX, Tracleer)*

12149K **BOSENTAN**, bosentan 125 mg tablet, 60 *(BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan GH, Bosentan Mylan, Bosentan RBX, Tracleer)*

13140N **BUROSUMAB**, burosumab 10 mg/mL injection, 1 mL vial *(Crysvita)*

13145W **BUROSUMAB**, burosumab 20 mg/mL injection, 1 mL vial *(Crysvita)*

13155J **BUROSUMAB**, burosumab 30 mg/mL injection, 1 mL vial *(Crysvita)*

10130E **EPOPROSTENOL**, epoprostenol 500 microgram injection, 1 vial *(Veletri)*

11090Q **EPOPROSTENOL**, epoprostenol 500 microgram injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack *(Flolan)*

10117L **EPOPROSTENOL**, epoprostenol 1.5 mg injection, 1 vial *(Veletri)*

11065J **EPOPROSTENOL**, epoprostenol 1.5 mg injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack *(Flolan)*

5751Q **ILOPROST**, iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules *(Ventavis)*

12147H **MACITENTAN**, macitentan 10 mg tablet, 30 *(Opsumit)*

13185Y **PEGCETACOPLAN**, pegcetacoplan 1.08 g/20 mL injection, 20 mL vial *(Empaveli)*

12144E **SILDENAFIL**, sildenafil 20 mg tablet, 90 *(Revatio, SILDATIO PHT, Sildenafil PHT APOTEX, Sildenafil Sandoz PHT 20)*

12151M **TADALAFIL**, tadalafil 20 mg tablet, 56 *(Adcirca, TADALIS 20, Tadalca)*

Deletion – Restriction

12212R **AMBRISENTAN**, ambrisentan 5 mg tablet, 30 *(Ambrisentan Mylan, Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris)*

12186J **AMBRISENTAN**, ambrisentan 10 mg tablet, 30 *(Ambrisentan Viatris, Cipla Ambrisentan, PULMORIS, Volibris)*

12145F **BOSENTAN**, bosentan 62.5 mg tablet, 60 *(BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Mylan, Bosentan RBX, Tracleer)*

12149K **BOSENTAN**, bosentan 125 mg tablet, 60 *(BOSENTAN DR.REDDY'S, BOSLEER, Bosentan APO, Bosentan Cipla, Bosentan GH, Bosentan Mylan, Bosentan RBX, Tracleer)*

13140N **BUROSUMAB**, burosumab 10 mg/mL injection, 1 mL vial *(Crysvita)*

13145W **BUROSUMAB**, burosumab 20 mg/mL injection, 1 mL vial *(Crysvita)*

13155J **BUROSUMAB**, burosumab 30 mg/mL injection, 1 mL vial *(Crysvita)*

10130E **EPOPROSTENOL**, epoprostenol 500 microgram injection, 1 vial *(Veletri)*

11090Q **EPOPROSTENOL**, epoprostenol 500 microgram injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack *(Flolan)*

10117L **EPOPROSTENOL**, epoprostenol 1.5 mg injection, 1 vial *(Veletri)*

11065J **EPOPROSTENOL**, epoprostenol 1.5 mg injection [1 vial] (&) inert substance diluent [2 x 50 mL vials], 1 pack *(Flolan)*

5751Q **ILOPROST**, iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules *(Ventavis)*

12147H **MACITENTAN**, macitentan 10 mg tablet, 30 *(Opsumit)*

13185Y **PEGCETACOPLAN**, pegcetacoplan 1.08 g/20 mL injection, 20 mL vial *(Empaveli)*

12144E **SILDENAFIL**, sildenafil 20 mg tablet, 90 *(Revatio, SILDATIO PHT, Sildenafil PHT APOTEX, Sildenafil Sandoz PHT 20)*

12151M **TADALAFIL**, tadalafil 20 mg tablet, 56 *(Adcirca, TADALIS 20, Tadalca)*

Advance Notices

1 June 2024

Deletion – Brand

12212R *Ambrisentan Mylan, AF* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30

5607D *Ambrisentan Mylan, AF* – **AMBRISENTAN**, ambrisentan 5 mg tablet, 30

12134P *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12140Y *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12145F *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

12149K *Tracleer, JC* – **BOSENTAN**, bosentan 125 mg tablet, 60

5618Q *Tracleer, JC* – **BOSENTAN**, bosentan 62.5 mg tablet, 60

5619R *Tracleer, JC* – **BOSENTAN**, bosentan 125 mg tablet, 60

9502D *Noumed Mycophenolate, VO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

1 August 2024

Deletion – Brand

12149K *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60

5619R *Bosentan Cipla, LR* – **BOSENTAN**, bosentan 125 mg tablet, 60

11885M *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

5623Y *Cinacalcet Mylan, AF* – **CINACALCET**, cinacalcet 90 mg tablet, 28

9501C *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 250 mg capsule, 100

9502D *CellCept, RO* – **MYCOPHENOLATE**, mycophenolate mofetil 500 mg tablet, 50

Highly Specialised Drugs Program (Community Access)

Deletions

Deletion – Brand

11149T *Tenofovir Disoproxil Emtricitabine Mylan 300/200, AF* – **TENOFOVIR DISOPROXIL + EMTRICITABINE**, tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30

Advance Notices

1 June 2024

Deletion – Brand

10284G *Lamivudine 150 mg + Zidovudine 300 mg Alphapharm, AF* – **LAMIVUDINE + ZIDOVUDINE**, lamivudine 150 mg + zidovudine 300 mg tablet, 60

General Pharmaceutical Benefits

▪ ABEMACICLIB

Note The Nottingham grading system is the histologic grading system developed by Elston and Ellis as a modification of the Scarff-Bloom-Richardson grading system. See the following literature publication for details:
Elston, CW, Ellis, IO. Pathological prognostic factors in breast cancer. The value of histological grade in breast cancer: experience from a large study with long-term follow-up. Histopathology. 1991 Nov;19(5):403-10.

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

Early breast cancer

Clinical criteria:

- The treatment must be adjuvant to surgical resection, **AND**
- The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing this drug, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system), **AND**
- The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 2 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression, **AND**
- The treatment must not be in combination with any of the following: (i) olaparib, (ii) pembrolizumab.

Treatment criteria:

- Patient must be undergoing concurrent treatment with endocrine therapy where this drug is being prescribed as a PBS benefit.

Retain all pathology imaging and investigative test results in the patient's medical records.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

abemaciclib 50 mg tablet, 56

14116Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4249.98	31.60	Verzenio [LY]

abemaciclib 100 mg tablet, 56

14105J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4249.98	31.60	Verzenio [LY]

abemaciclib 150 mg tablet, 56

14134X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4249.98	31.60	Verzenio [LY]

▪ ABEMACICLIB

Note Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

Note Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

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

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- 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, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

abemaciclib 50 mg tablet, 56

11876C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4249.98	31.60	Verzenio [LY]

abemaciclib 100 mg tablet, 56

11871T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4249.98	31.60	Verzenio [LY]

abemaciclib 150 mg tablet, 56

11868P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4249.98	31.60	Verzenio [LY]

▪ ALIROCUMAB

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 (STREAMLINED)

15201

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

Authority required (STREAMLINED)

15177

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

alirocumab 150 mg/mL injection, 2 x 1 mL pen devices

12608N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	499.16	31.60	Praluent [SW]

alirocumab 75 mg/mL injection, 2 x 1 mL pen devices

12607M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	499.16	31.60	Praluent [SW]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT VALINE, LEUCINE, ISOLEUCINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

Restricted benefit

Maple syrup urine disease

amino acid formula with vitamins and minerals without valine, leucine, isoleucine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets

14118C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*1743.33	31.60	MSUD explore5 [VF]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT METHIONINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

Restricted benefit

Pyridoxine non-responsive homocystinuria

amino acid formula with vitamins and minerals, without methionine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets

14114W NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*1743.33	31.60	HCU explore5 [VF]

▪ AMINO ACID FORMULA WITH VITAMINS AND MINERALS, WITHOUT PHENYLALANINE, TYROSINE AND SUPPLEMENTED WITH ARACHIDONIC ACID AND DOCOSAHEXAENOIC ACID

Restricted benefit

Tyrosinaemia

amino acid formula with vitamins and minerals, without phenylalanine, tyrosine and supplemented with arachidonic acid and docosahexaenoic acid containing 5 g of protein equivalent powder for oral liquid, 30 x 12.5 g sachets

14126L NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
8	5	..	*1743.33	31.60	TYR explore5 [VF]

▪ COLESTYRAMINE

colestyramine 4 g powder for oral liquid, 60 pouches

14132T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*253.11	31.60	Cholestyramine (Ascend, USA) [CR]

▪ COLESTYRAMINE

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.

Restricted benefit

Primary hypercholesterolaemia

Clinical criteria:

- Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements.

colestyramine 4 g powder for oral liquid, 60 pouches

14145L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	11	..	*253.11	31.60	Cholestyramine (Ascend, USA) [CR]

▪ EVOLOCUMAB

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 (STREAMLINED)

15201

Non-familial hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

Authority required (STREAMLINED)

15177

Familial heterozygous hypercholesterolaemia

Treatment Phase: Continuing treatment with this drug or switching treatment from any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must have received PBS-subsidised treatment for this PBS indication with any of: (i) a drug from the same pharmacological class as this drug (ii) inclisiran, **AND**
- The treatment must be in conjunction with dietary therapy and exercise, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with any of: (i) another drug that belongs to the same pharmacological class as this drug, (ii) inclisiran, for this PBS indication.

evolocumab 140 mg/mL injection, 1 mL pen device

11985T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*338.79	31.60	Repatha [AN]

evolocumab 420 mg/3.5 mL injection, 3.5 mL cartridge

11986W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	366.21	31.60	Repatha [AN]

▪ MAVACAMTEN

Caution The patient's condition should be assessed prior to receiving treatment and closely monitored throughout the treatment period.

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 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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: First continuing treatment (until at least 6 months on optimal dose is achieved)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the grandfather treatment restriction if dose titration or 6 months on optimal dose is yet to be achieved, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must be titrating mavacamten treatment until optimal dose is achieved; OR
- Patient must be continuing mavacamten treatment to reach at least 6 months on the optimal dose prior to assessing the response.

Treatment criteria:

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

The assessment of response must be conducted after at least 6 months on optimal dose to determine the patient's eligibility for maintenance treatment. Where an assessment is not undertaken, the patient will not be eligible for ongoing treatment. This treatment phase listing intends to provide up to 36 weeks of treatment in 3 treatment courses.

For the purposes of this restriction, an adequate response to treatment is defined as: an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.

mavacamten 10 mg capsule, 28

14137C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	2322.83	31.60	Camzyos [BQ]

mavacamten 15 mg capsule, 28

14139E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	2322.83	31.60	Camzyos [BQ]

▪ MAVACAMTEN

Caution The patient's condition should be assessed prior to receiving treatment and closely monitored throughout the treatment period.

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

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: Initial treatment (covering the first 12 weeks of therapy)

Clinical criteria:

- Patient must have confirmed left ventricular hypertrophy due to hypertrophic cardiomyopathy, **AND**
- Patient must have maximal end-diastolic left ventricular wall thickness which is at least one of either: (i) no less than 15 mm; (ii) no less than 13 mm if patient has familial hypertrophic cardiomyopathy (at least one first degree relative with a diagnosis of hypertrophic cardiomyopathy), **AND**
- Patient must have confirmed peak left ventricular outflow tract (LVOT) gradient of no less than 50 mm Hg which is measured either: (i) at rest; (ii) after provocation with at least one of (a) Valsalva manoeuvre, (b) exercise, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 55%, **AND**
- Patient must have had prior treatments with each of a (i) beta-blocker and (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must be symptomatic with NYHA classes II or III.

Treatment criteria:

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include all the following:

(1) A completed authority prescription form; and

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(3) The details of the echocardiogram and/ or cardiac magnetic resonance imaging (MRI) report confirming the diagnosis of hypertrophic cardiomyopathy (HCM). State all the following:

(a) the date, unique identifying number/code or provider number of the report;

(b) the left ventricular wall thickness in millimetres (mm).

(4) The details of a genotyping test report if the patient had been tested. State all the following:

(a) the date, unique identifying number/code or provider number of the report;

(b) if a gene has been identified that is associated with HCM;

(c) if any first-degree family relative has a confirmed diagnosis of HCM.

(5) The details of the LVOT gradient report. State all the following:

(a) the date, unique identifying number/code or provider number of the report;

(b) the measured LVOT gradient;

(c) how the LVOT gradient was measured (rest, Valsalva manoeuvre or exercise).

(6) NYHA status.

(7) The current beta-blocker or non-dihydropyridine calcium channel blocker (either diltiazem or verapamil only) therapy if applicable.

(8) Prior beta-blocker or non-dihydropyridine calcium channel blocker trials, including:

(a) if the patient is currently taking beta-blocker therapy, state the previous therapy with non-dihydropyridine calcium channel blocker that was trialled confirming that it was not effective;

(b) if the patient is currently taking non-dihydropyridine calcium channel blocker therapy, state the previous therapy with beta-blocker that was trialled confirming that it was not effective;

(c) if there is contraindication or intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information, specify the details.

All results and reports must be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: First continuing treatment (until at least 6 months on optimal dose is achieved)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the grandfather treatment restriction if dose titration or 6 months on optimal dose is yet to be achieved, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must be titrating mavacamten treatment until optimal dose is achieved; OR
- Patient must be continuing mavacamten treatment to reach at least 6 months on the optimal dose prior to assessing the response.

Treatment criteria:

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

The assessment of response must be conducted after at least 6 months on optimal dose to determine the patient's eligibility for maintenance treatment. Where an assessment is not undertaken, the patient will not be eligible for ongoing treatment. This treatment phase listing intends to provide up to 36 weeks of treatment in 3 treatment courses.

For the purposes of this restriction, an adequate response to treatment is defined as: an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.

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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

mavacamten 2.5 mg capsule, 28

14135Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	2322.83	31.60	Camzyos [BQ]

mavacamten 5 mg capsule, 28

14117B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	2322.83	31.60	Camzyos [BQ]

▪ MAVACAMTEN

Caution The patient's condition should be assessed prior to receiving treatment and closely monitored throughout the treatment period.

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

Symptomatic obstructive hypertrophic cardiomyopathy

Treatment Phase: Subsequent continuing treatment - Maintenance treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; OR
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the grandfather arrangements if at least 6 months on optimal dose is achieved, **AND**

- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must have demonstrated a response after at least 6 months on the optimal dose of mavacamten treatment defined as an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) peak left ventricular outflow tract (LVOT) gradient.

Treatment criteria:

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Symptomatic obstructive hypertrophic cardiomyopathy

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- Patient must have had confirmed left ventricular hypertrophy due to hypertrophic cardiomyopathy prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must have had maximal end-diastolic left ventricular wall thickness, prior to commencing non-PBS-subsidised treatment, which is at least one of either: (i) no less than 15 mm; (ii) no less than 13 mm if patient has familial hypertrophic cardiomyopathy (at least one first degree relative with a diagnosis of hypertrophic cardiomyopathy), **AND**
- Patient must have had confirmed peak left ventricular outflow tract (LVOT) gradient, prior to commencing non-PBS-subsidised treatment, of no less than 50 mm Hg which is measured either: (i) at rest; (ii) after provocation with at least one of: (a) Valsalva manoeuvre; (b) exercise, **AND**
- Patient must have had left ventricular ejection fraction (LVEF) of no less than 55% prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must have had prior treatments with each of a (i) beta-blocker and (ii) non-dihydropyridine calcium channel blocker, unless contraindication/ intolerance present, prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must have been symptomatic with NYHA classes II or III prior to commencing non-PBS-subsidised treatment, **AND**
- Patient must be undergoing concomitant treatment with at least one of: (i) a beta-blocker (ii) non-dihydropyridine calcium channel blocker, unless at least one of the following is present: (a) a contraindication to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information; (b) an intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy, **AND**
- Patient must have a current left ventricular ejection fraction (LVEF) of no less than 50%, **AND**
- Patient must have demonstrated a response if received the optimal dose of mavacamten treatment for at least 6 months, defined as an improvement in at least one of the following: (i) symptoms, (ii) quality of life, (iii) exercise capacity, (iv) LVOT gradient; OR
- Patient must be receiving mavacamten treatment but have not reached at least 6 months on optimal dose to demonstrate a response as defined above.

Treatment criteria:

- Must be treated by a cardiologist; OR
- Must be treated by a consultant physician with experience in the management of hypertrophic cardiomyopathy.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include all the following:

(1) A completed authority prescription form; and

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(3) The details of the echocardiogram and/ or cardiac magnetic resonance imaging (MRI) report confirming the diagnosis of hypertrophic cardiomyopathy (HCM). State all the following:

(a) the date, unique identifying number/code or provider number of the report;

(b) the left ventricular wall thickness in millimetres (mm).

(4) The details of a genotyping test report if the patient had been tested. State all the following:

(a) the date, unique identifying number/code or provider number of the report;

(b) if a gene has been identified that is associated with HCM;

(c) if any first-degree family relative has a confirmed diagnosis of HCM.

(5) The details of the LVOT gradient report. State all the following:

(a) the date, unique identifying number/code or provider number of the report;

(b) the measured LVOT gradient;

(c) how the LVOT gradient was measured (rest, Valsalva manoeuvre or exercise).

(6) NYHA status.

(7) The current beta-blocker or non-dihydropyridine calcium channel blocker (either diltiazem or verapamil only) therapy if applicable.

(8) Prior beta-blocker or non-dihydropyridine calcium channel blocker trials, including:

(a) if the patient is currently taking beta-blocker therapy, state the previous therapy with non-dihydropyridine calcium channel blocker that was trialled confirming that it was not effective;

(b) if the patient is currently taking non-dihydropyridine calcium channel blocker therapy, state the previous therapy with beta-blocker that was trialled confirming that it was not effective;

(c) if there is contraindication or intolerance to beta-blocker and/or non-dihydropyridine calcium channel blocker therapy as listed in the TGA approved Product Information, specify the details.

All results and reports must be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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 'maintenance treatment' criteria if at least 6 months on optimal dose of mavacamten treatment is achieved. Where a 'Grandfathered' patient has received fewer than 6 months on optimal dose, or is titrating treatment until optimal dose is achieved, they must qualify under the 'first continuing treatment' criteria.

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

mavacamten 10 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14138D	1	5	..	2322.83	31.60	Camzyos [BQ]

mavacamten 15 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14124J	1	5	..	2322.83	31.60	Camzyos [BQ]

mavacamten 2.5 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14123H	1	5	..	2322.83	31.60	Camzyos [BQ]

mavacamten 5 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
14113T	1	5	..	2322.83	31.60	Camzyos [BQ]

▪ NIRAPARIB

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 Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of 3 capsules

Clinical criteria:

- The treatment must be continuing existing PBS-subsidised treatment with this drug initiated through the Treatment Phase: Initial first-line maintenance therapy (**BRCA1/2** gene mutation), **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

niraparib 100 mg capsule, 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13079J	1	5	..	9874.39	31.60	Zejula [GK]

▪ NIRAPARIB

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 Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuation of first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules

Clinical criteria:

- Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.

niraparib 100 mg capsule, 56

14094T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	6636.97	31.60	Zejula [GK]

▪ NIRAPARIB

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Definitions:
Class 5 - Pathogenic
Class 4 - Likely pathogenic
Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

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 Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules

Clinical criteria:

- The condition must be associated with a pathogenic variant (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** gene(s) - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.

niraparib 100 mg capsule, 56

13089X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	6636.97	31.60	Zejula [GK]

▪ NIRAPARIB

Note This drug belongs to the poly (ADP-ribose) polymerase (PARP) inhibitor drug class. The restriction refers to the following PARP inhibitors: olaparib, niraparib

Note Definitions:
Class 5 - Pathogenic
Class 4 - Likely pathogenic
Tier I - variants of strong clinical significance
Tier II - variants of potential clinical significance

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 Special Pricing Arrangements apply.

Authority required

High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial first-line maintenance therapy (genomic instability without BRCA1/2 gene mutation) in a patient requiring a daily dose of up to 2 capsules

Clinical criteria:

- The condition must be associated with homologous recombination deficiency (HRD) positive status defined by genomic instability, which has been confirmed by a validated test, **AND**
- The condition must not be associated with pathogenic variants (germline mutation class 4/class 5; somatic mutation classification tier I/tier II) of the **BRCA1/2** genes - this has been confirmed by a validated test, **AND**
- Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; OR
- The condition must have both: (i) been in a partial/complete response to the immediately preceding platinum-based chemotherapy regimen prior to having commenced non-PBS-subsidised treatment with this drug for this condition, (ii) not progressed since the commencement of non-PBS-subsidised supply of this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug class for the first time; OR
- Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.

A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.

Evidence of homologous recombination deficiency (genomic instability) must be derived through a test that has been validated against the Myriad MyChoice HRD assay, which uses a score of 42 or greater as the threshold for HRD (genomic instability) positivity.

Evidence that BRCA1/2 gene mutations are absent must also be derived through a validated test as described above.

niraparib 100 mg capsule, 56

14088L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	6636.97	31.60	Zejula [GK]

▪ ONDANSETRON

Authority required (STREAMLINED)

15193

Nausea and vomiting

Clinical criteria:

- The condition must be associated with radiotherapy being used to treat malignancy; OR
- The condition must be associated with chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions.

ondansetron 4 mg/5 mL oral liquid, 50 mL

8233H

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡1	1	..	99.84	31.60	Zofran syrup 50 mL [AS]

ondansetron 4 mg tablet, 10

1594X

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	22.40	23.80	[a] APO-Ondansetron [TX]	[a] APX-Ondansetron [TY]
					[a] Ondansetron-DRLA [RZ]	[a] Ondansetron Mylan Tablets [AF]
					[a] Ondansetron SZ [HX]	[a] Zofran [AS]
					[a] Zotren 4 [RF]	

ondansetron 8 mg tablet, 10

1595Y

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	24.63	26.03	[a] APO-Ondansetron [TX]	[a] APX-Ondansetron [TY]
					[a] Ondansetron-DRLA [RZ]	[a] Ondansetron Mylan Tablets [AF]
					[a] Ondansetron SZ [HX]	[a] Zofran [AS]
					[a] Zotren 8 [RF]	

▪ ONDANSETRON

Note Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 4 mg and pharmaceutical benefits that have the form ondansetron 4 mg wafer are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

15193

Nausea and vomiting

Clinical criteria:

- The condition must be associated with radiotherapy being used to treat malignancy; OR
- The condition must be associated with chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions.

ondansetron 4 mg orally disintegrating tablet, 10

5472B

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	22.40	23.80	[a] APX-Ondansetron ODT [TY]	[a] Ondansetron Mylan ODT [AF]
					[a] Ondansetron ODT-DRLA [RZ]	[a] Ondansetron ODT Lupin [HQ]
					[a] Ondansetron SZ ODT [HX]	[a] Zotren ODT [RF]

ondansetron 4 mg wafer, 10

8412R

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	[B]3.46	25.86	23.80	[a] Zofran Zydis [AS]

▪ ONDANSETRON

Note Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 8 mg and pharmaceutical benefits that have the form ondansetron 8 mg wafer are equivalent for the purposes of substitution.

Authority required (STREAMLINED)

15193

Nausea and vomiting

Clinical criteria:

- The condition must be associated with radiotherapy being used to treat malignancy; OR
- The condition must be associated with chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions.

ondansetron 8 mg orally disintegrating tablet, 10

5473C NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	1	..	24.63	26.03	[a] APX-Ondansetron ODT [TY]	[a] Ondansetron Mylan ODT [AF]
					[a] Ondansetron ODT-DRLA [RZ]	[a] Ondansetron ODT Lupin [HQ]
					[a] Ondansetron SZ ODT [HX]	[a] Zotren ODT [RF]

ondansetron 8 mg wafer, 10

8413T NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	[B]3.45	30.83	28.78	[a] Zofran Zydis [AS]

▪ PALBOCICLIB

Note Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

Note Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

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

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with a non-steroidal aromatase inhibitor; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- 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, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

palbociclib 100 mg tablet, 21

12819Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4249.98	31.60	Ibrance [PF]

palbociclib 125 mg tablet, 21

12822W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4249.98	31.60	Ibrance [PF]

palbociclib 75 mg tablet, 21

12818P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	4249.98	31.60	Ibrance [PF]

▪ PERAMPANEL

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

Note Special Pricing Arrangements apply.

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.

Authority required (STREAMLINED)

14847

Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Population criteria:

- Patient must be aged 12 years or older.

perampanel 6 mg tablet, 28

14046G

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*450.79	31.60	Fycompa [EI]

perampanel 4 mg tablet, 28

13864Q

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*303.19	31.60	Fycompa [EI]

▪ PROCHLORPERAZINE

Caution Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

Note Pharmaceutical benefits that have the form prochlorperazine maleate, 5 mg tablet can be substituted for prochlorperazine maleate 5 mg tablet Stemetil (Ireland) in the case of a shortage.

prochlorperazine maleate 5 mg tablet, 250

14108M

DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.1	..	..	*33.18	31.60	[a] Stemetil (Ireland) [OJ]

prochlorperazine maleate 5 mg tablet, 25

5205Y

DP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	15.90	17.30	[a] APO-Prochlorperazine [TX] [a] Prochlorperazine GH [GQ]	[a] ProCalm [RW]
		[B]2.79	18.69	17.30	[a] Stemetil [SW]	

▪ PROCHLORPERAZINE

Caution Prochlorperazine may be associated with parkinsonism and tardive dyskinesia and should be used for short-term treatment only.

Note As prochlorperazine may be associated with parkinsonism and tardive dyskinesia it should be used for short-term treatment only. However, authorities for increased maximum quantities and/or repeats of prochlorperazine tablets will be granted for the treatment of emesis associated with malignant disease.

Note Pharmaceutical benefits that have the form prochlorperazine maleate, 5 mg tablet can be substituted for prochlorperazine maleate 5 mg tablet Stemetil (Ireland) in the case of a shortage.

prochlorperazine maleate 5 mg tablet, 250

14129P

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
0.1	..	..	*33.18	31.60	[a] Stemetil (Ireland) [OJ]

prochlorperazine maleate 5 mg tablet, 25

2893G

NP

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	15.90	17.30	[a] APO-Prochlorperazine [TX] [a] Prochlorperazine GH [GQ]	[a] ProCalm [RW]
		[B]2.79	18.69	17.30	[a] Stemetil [SW]	

▪ RIBOCICLIB

Caution QT interval monitoring is required for patients treated with this drug.

Note Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

Note Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

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

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- 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, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- Patient must require dosage reduction requiring a pack of 21 tablets, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

ribociclib 200 mg tablet, 21

11385F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1847.04	31.60	Kisqali [NV]

▪ RIBOCICLIB

Caution QT interval monitoring is required for patients treated with this drug.

Note Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

Note Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

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

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- 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, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

ribociclib 200 mg tablet, 63

11386G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	5254.15	31.60	Kisqali [NV]

▪ RIBOCICLIB

Caution QT interval monitoring is required for patients treated with this drug.

Note Non-steroidal aromatase inhibitors for the purposes of this restriction are anastrozole and letrozole.

Note Cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors for the purposes of this restriction are abemaciclib, palbociclib and ribociclib.

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

Locally advanced or metastatic breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR
- Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, **AND**
- The condition must be hormone receptor positive, **AND**
- The condition must be human epidermal growth factor receptor 2 (HER2) negative, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of (i) a non-steroidal aromatase inhibitor, (ii) fulvestrant; OR
- The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 42 tablets.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

Authority required

Locally advanced or metastatic breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- 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, **AND**
- The treatment must be in combination with one of: (i) non-steroidal aromatase inhibitor, (ii) fulvestrant, **AND**
- The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy, **AND**
- Patient must require dosage reduction requiring a pack of 42 tablets.

Population criteria:

- Patient must not be premenopausal.

PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

ribociclib 200 mg tablet, 42

11397W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	3556.81	31.60	Kisqali [NV]

▪ RISANKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of

more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

risankizumab 150 mg/mL injection, 1 mL pen device

14142H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	..	5401.42	31.60	Skyrizi [VE]

▪ RISANKIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.
A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.
A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.
A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.
Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.
Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.
A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.
Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.
The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.
A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.
There is no limit to the number of treatment cycles a patient may undertake in their lifetime.
How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.
There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.
(1) Initial treatment.

An application for initial treatment should be made where:
(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or
(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or
(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).
(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).
An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.
It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.
(2) Assessment of response to initial treatment.
When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.
The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.
(3) Continuing treatment.
Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
Infliximab, adalimumab and etanercept only:
For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.
For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.
(4) Swapping therapy.
Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.
A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.
A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.
To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.
(5) Baseline measurements to determine response.
A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.
To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.
(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.
A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
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HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have 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**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
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Or mailed to:
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Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
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Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.

Treatment criteria:

- Must be treated by a dermatologist.

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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

risankizumab 150 mg/mL injection, 1 mL pen device

14111Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	2	..	5401.42	31.60	Skyrizi [VE]

▪ TAFAMIDIS

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

Transthyretin amyloid cardiomyopathy

Treatment Phase: First PBS-subsidised prescription for this drug

Clinical criteria:

- The treatment must be for wild-type transthyretin-mediated amyloid cardiomyopathy, with documented evidence of transthyretin precursor protein present; OR
- The treatment must be for variant transthyretin-mediated (also known as hereditary transthyretin-mediated) amyloid cardiomyopathy, with documented evidence of transthyretin precursor protein present, **AND**
- Patient must have experienced at least one episode of hospitalisation that was a direct result of heart failure; OR
- Patient must have clinical evidence of heart failure without hospitalisation that required treatment with a diuretic for improvement, **AND**
- Patient must have/have had New York Heart Association class I heart failure at the time of commencing this drug; OR
- Patient must have/have had New York Heart Association class II heart failure at the time of commencing this drug, **AND**
- Patient must have an end-diastolic interventricular septal wall thickness of at least 12 mm on imaging, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 m^2.

Treatment criteria:

- Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Evidence of clinical findings to establish the diagnosis:

In this authority application, confirm that there is documented evidence of transthyretin precursor protein through either (1) alone, or, both (2) and (3), from the list below:

Confirm the following has been completed:

(1) amyloid expert centre histology findings derived via immunohistochemistry or mass spectrometry; OR

(2) bone scintigraphy with grade 2-3 finding AND

(3) Confirm that there are negative results for monoclonal protein on each of the following three tests:

(a) serum immunofixation (also known as protein electrophoresis)

(b) urine immunofixation

(c) serum free light chains blood test

State which of (1) to (3) above has been completed, as well as the:

(i) date of the finding,

(ii) imaging/pathology report number/code that links the finding to the patient,

(iii) name of the amyloid expert centre in this authority application.

For end-diastolic interventricular septal wall thickness (at least 12 mm), confirm that:

(i) imaging (echocardiogram or magnetic resonance imaging) has been undertaken; and

(ii) that the imaging report is stored in the patient's medical records.

State the date that the imaging was performed and the thickness (in mm) in this authority application.

Where this authority application is to transition a patient from non-PBS-subsidised to PBS-subsidised supply (i.e. a 'grandfathered' patient), confirm the following:

(i) the patient's heart failure has not worsened to persistent New York Heart Association Class III/IV heart failure while taking this drug.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note The Australian Amyloid Network provides a list of clinic centres that manage amyloidosis. It also provides a list of Australian anatomical pathology laboratories to be contacted for tissue review and immunohistochemistry for amyloid typing. For the purposes of this restriction, these providers are considered to be amyloid expert centres.

Authority required

Transthyretin amyloid cardiomyopathy

Treatment Phase: Second and subsequent PBS-subsidised prescriptions for this drug

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 m^2, **AND**
- The treatment must be ceased where the patient's heart failure has worsened to persistent New York Heart Association (NYHA) Class III/IV heart failure, **AND**
- The treatment must be ceased where the patient has received any of: (i) a heart transplant, (ii) a liver transplant, (iii) an implanted ventricular assist device.

Treatment criteria:

- Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment.

Confirm whether heart failure has worsened to NYHA Class III/IV since the last authority application (yes/no).

If 'no', continued PBS subsidy is available.

If 'yes', continued PBS subsidy is available, but the prescriber must undertake a review of the patient within 3 months to determine whether the worsening heart failure was transient or persistent. Prescribe no more than 2 repeat prescriptions in such an instance.

Where this subsequent clinical review finds that the heart failure persists as NYHA Class III/IV heart failure despite active treatment with this drug, then PBS subsidy is not available.

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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

tafamidis 61 mg capsule, 30

14100D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	10022.13	31.60	Vyndamax [PF]

▪ UPADACITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

upadacitinib 15 mg modified release tablet, 28

14125K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1272.31	31.60	Rinvoq [VE]

▪ UPADACITINIB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under
Initiating subsidy:
(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.
Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.
The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.
(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.
Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.
Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.
Continuing subsidy:
Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.
The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.
'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.
Balance of Supply listings:
Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.
Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.
(2) Baseline measurements to determine response.
Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.
To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.
Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.
Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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

Severe active rheumatoid arthritis

Treatment Phase: First Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe active rheumatoid arthritis

Treatment Phase: First Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

upadacitinib 15 mg modified release tablet, 28

11979L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1272.31	31.60	Rinvoq [VE]

Highly Specialised Drugs Program (Private Hospital)

▪ DIFELIKEFALIN

Note See the following article for details on the 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS):
Vernon MK, Swett LL, Speck RM, et al. Psychometric validation and meaningful change thresholds of the Worst Itching Intensity Numerical Rating Scale for assessing itch in patients with chronic kidney disease-associated pruritus. J Patient Rep Outcomes. 2021;5(1):134. Published 2021 Dec 24. doi:10.1186/s41687-021-00404-z
The WI-NRS scale is available as downloadable document in the supplementary information section at:
www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/

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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe pruritus (itching) associated with chronic kidney disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be on optimised haemodialysis, **AND**
- Patient must be on haemodialysis for at least 3 months, **AND**
- The condition must be confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus, **AND**
- Patient must have experienced itch that persists for at least 6 weeks despite best supportive care, **AND**
- Patient must have a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) baseline score of more than 4, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a nephrologist.

Population criteria:

- Patient must be at least 18 years of age.

Prescriber must exclude any other causes of pruritus which include any of the following:

(i) drug/dialysis related (e.g., opioid-related pruritus);

(ii) drug hypersensitivity or adverse effect; contact dermatitis; allergy;

(iii) differential diagnoses (e.g., xerosis; infestations; iron deficiency; liver disease; polycythaemia vera/leukemia/lymphoma; hypothyroidism; uncontrolled diabetes).

Best supportive care for patients with chronic kidney disease-associated pruritus is not limited to but includes:

(i) optimisation of dialysis;

(ii) skin hydration and nutrition (with the use of moisturiser, emollients, barrier creams or oils);

(iii) patient education on the importance of avoiding or minimising scratching.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 2 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

difelikefalin 50 microgram/mL injection, 12 x 1 mL vials

14110P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	569.97	Korsuva [CS]

▪ DIFELIKEFALIN

Note See the following article for details on the 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS):
Vernon MK, Swett LL, Speck RM, et al. Psychometric validation and meaningful change thresholds of the Worst Itching Intensity Numerical Rating Scale for assessing itch in patients with chronic kidney disease-associated pruritus. J Patient Rep Outcomes. 2021;5(1):134. Published 2021 Dec 24. doi:10.1186/s41687-021-00404-z

The WI-NRS scale is available as downloadable document in the supplementary information section at: www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/

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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe pruritus (itching) associated with chronic kidney disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score.

Treatment criteria:

- Must be treated by a nephrologist; OR
- Must be treated by a medical practitioner in consultation with a nephrologist.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

Authority required

Moderate to severe pruritus (itching) associated with chronic kidney disease

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS-subsidised supply was commenced, the patient: (i) was on optimised haemodialysis; (ii) was on haemodialysis for at least 3 months; (iii) had a condition confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus; (iv) had experienced itch that persists for at least 6 weeks despite best supportive care; (v) had a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) of more than 4 at baseline, **AND**
- Patient must have demonstrated an adequate response to the most recent non-PBS-subsidised treatment with this drug for this condition, including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score.

Treatment criteria:

- Must be treated by a nephrologist.

Population criteria:

- Patient must be at least 18 years of age.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

Note 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.

difelikefalin 50 microgram/mL injection, 12 x 1 mL vials

14106K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	569.97	Korsuva [CS]

▪ ELTROMBOPAG

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe aplastic anaemia

Treatment Phase: Initial treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; OR
- Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) prior immunosuppressive therapy, including dates of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

eltrombopag 25 mg tablet, 28

14115X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	3	..	*3732.72	Revolade [NV]

▪ ELTROMBOPAG

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

Note Special Pricing Arrangements apply.

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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe aplastic anaemia

Treatment Phase: Continuing treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must have demonstrated a response to PBS-subsidised treatment with this drug.

Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Once platelet count is greater than 50 x 10^9/L, haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than 1 x 10^9/L for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information.

For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.

eltrombopag 25 mg tablet, 28

14119D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	5	..	*3732.72	Revolade [NV]

▪ ELTROMBOPAG

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 Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe aplastic anaemia

Treatment Phase: Initial treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**

- Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; OR
- Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) prior immunosuppressive therapy, including dates of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

eltrombopag 50 mg tablet, 28

14107L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	3	..	*7417.08	Revolade [NV]

▪ ELTROMBOPAG

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 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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe aplastic anaemia

Treatment Phase: Continuing treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must have demonstrated a response to PBS-subsidised treatment with this drug.

Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Once platelet count is greater than 50 x 10^9/L, haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than 1 x 10^9/L for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information.

For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.

eltrombopag 50 mg tablet, 28

14143J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	5	..	*7417.08	Revolade [NV]

▪ ELTROMBOPAG

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe aplastic anaemia

Treatment Phase: First line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority required

Severe aplastic anaemia

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition prior to initiating non-PBS-subsidised treatment, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

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

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

eltrombopag 25 mg tablet, 28

14136B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	5	..	*3732.72	Revolade [NV]

▪ ELTROMBOPAG

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 Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe aplastic anaemia

Treatment Phase: First line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority required

Severe aplastic anaemia

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition prior to initiating non-PBS-subsidised treatment, **AND**

- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

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

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

eltrombopag 50 mg tablet, 28

14127M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	5	..	*7417.08	Revolade [NV]

Highly Specialised Drugs Program (Public Hospital)

▪ DIFELIKEFALIN

Note See the following article for details on the 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS):
Vernon MK, Swett LL, Speck RM, et al. Psychometric validation and meaningful change thresholds of the Worst Itching Intensity Numerical Rating Scale for assessing itch in patients with chronic kidney disease-associated pruritus. J Patient Rep Outcomes. 2021;5(1):134. Published 2021 Dec 24. doi:10.1186/s41687-021-00404-z
The WI-NRS scale is available as downloadable document in the supplementary information section at:
www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/

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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe pruritus (itching) associated with chronic kidney disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be on optimised haemodialysis, **AND**
- Patient must be on haemodialysis for at least 3 months, **AND**
- The condition must be confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus, **AND**
- Patient must have experienced itch that persists for at least 6 weeks despite best supportive care, **AND**
- Patient must have a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) baseline score of more than 4, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a nephrologist.

Population criteria:

- Patient must be at least 18 years of age.

Prescriber must exclude any other causes of pruritus which include any of the following:

(i) drug/dialysis related (e.g., opioid-related pruritus);

(ii) drug hypersensitivity or adverse effect; contact dermatitis; allergy;

(iii) differential diagnoses (e.g., xerosis; infestations; iron deficiency; liver disease; polycythaemia vera/leukemia/lymphoma; hypothyroidism; uncontrolled diabetes).

Best supportive care for patients with chronic kidney disease-associated pruritus is not limited to but includes:

(i) optimisation of dialysis;

(ii) skin hydration and nutrition (with the use of moisturiser, emollients, barrier creams or oils);

(iii) patient education on the importance of avoiding or minimising scratching.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 2 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

difelikefalin 50 microgram/mL injection, 12 x 1 mL vials

14140F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	..	540.00	Korsuva [CS]

▪ DIFELIKEFALIN

Note See the following article for details on the 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS):
Vernon MK, Swett LL, Speck RM, et al. Psychometric validation and meaningful change thresholds of the Worst Itching Intensity Numerical Rating Scale for assessing itch in patients with chronic kidney disease-associated pruritus. J Patient Rep Outcomes. 2021;5(1):134. Published 2021 Dec 24. doi:10.1186/s41687-021-00404-z

The WI-NRS scale is available as downloadable document in the supplementary information section at: www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/

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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe pruritus (itching) associated with chronic kidney disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score.

Treatment criteria:

- Must be treated by a nephrologist; OR
- Must be treated by a medical practitioner in consultation with a nephrologist.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

Authority required

Moderate to severe pruritus (itching) associated with chronic kidney disease

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS-subsidised supply was commenced, the patient: (i) was on optimised haemodialysis; (ii) was on haemodialysis for at least 3 months; (iii) had a condition confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus; (iv) had experienced itch that persists for at least 6 weeks despite best supportive care; (v) had a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) of more than 4 at baseline, **AND**
- Patient must have demonstrated an adequate response to the most recent non-PBS-subsidised treatment with this drug for this condition, including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score.

Treatment criteria:

- Must be treated by a nephrologist.

Population criteria:

- Patient must be at least 18 years of age.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

Note 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.

difelikefalin 50 microgram/mL injection, 12 x 1 mL vials

14141G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	..	540.00	Korsuva [CS]

▪ ELTROMBOPAG

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

Note Special Pricing Arrangements apply.

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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe aplastic anaemia

Treatment Phase: Continuing treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must have demonstrated a response to PBS-subsidised treatment with this drug.

Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Once platelet count is greater than 50 x 10^9/L, haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than 1 x 10^9/L for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information.

For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.

eltrombopag 25 mg tablet, 28

14120E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	5	..	*3684.36	Revolade [NV]

▪ ELTROMBOPAG

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe aplastic anaemia

Treatment Phase: Initial treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; OR
- Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) prior immunosuppressive therapy, including dates of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

eltrombopag 25 mg tablet, 28

14144K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	3	..	*3684.36	Revolade [NV]

▪ ELTROMBOPAG

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 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 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Severe aplastic anaemia

Treatment Phase: Continuing treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must have demonstrated a response to PBS-subsidised treatment with this drug.

Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Once platelet count is greater than 50 x 10^9/L, haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than 1 x 10^9/L for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information.

For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.

eltrombopag 50 mg tablet, 28

14112R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	5	..	*7368.72	Revolade [NV]

▪ ELTROMBOPAG

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 Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe aplastic anaemia

Treatment Phase: Initial treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; OR
- Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) prior immunosuppressive therapy, including dates of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

eltrombopag 50 mg tablet, 28

14121F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	3	..	*7368.72	Revolade [NV]

▪ ELTROMBOPAG

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe aplastic anaemia

Treatment Phase: First line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**

- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority required

Severe aplastic anaemia

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition prior to initiating non-PBS-subsidised treatment, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

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

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

eltrombopag 25 mg tablet, 28

14128N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	5	..	*3684.36	Revolade [NV]

▪ ELTROMBOPAG

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 Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Severe aplastic anaemia

Treatment Phase: First line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority required

Severe aplastic anaemia

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- The condition must be severe aplastic anaemia, **AND**

- Patient must not have received treatment with immunosuppressive therapy for this condition prior to initiating non-PBS-subsidised treatment, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

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

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

eltrombopag 50 mg tablet, 28

14131R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	5	..	*7368.72	Revolade [NV]