



Australian Government

Department of Health

**SCHEDULE OF PHARMACEUTICAL
BENEFITS**

SUMMARY OF CHANGES

EFFECTIVE 1 December 2013

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 December 2013. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 December 2013 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.63
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.67
	Allowable additional patient charge*	\$4.11
Additional Fees (for safety net prices):	Ready-prepared	\$1.13
	Extemporaneously-prepared	\$1.48
Patient Co-payments:	General	\$36.10
	Concessional	\$5.90
Safety Net Thresholds:	General	\$1390.60
	Concessional	\$354.00
Safety Net Card Issue Fee:		\$9.06

*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

Additions

Addition – Item

2944Y	Alogliptin , alogliptin 6.25 mg tablet, 28 (<i>Nesina</i>)
2933J	Alogliptin , alogliptin 12.5 mg tablet, 28 (<i>Nesina</i>)
2986E	Alogliptin , alogliptin 25 mg tablet, 28 (<i>Nesina</i>)
2928D	Amino Acid Synthetic Formula Supplemented With Long Chain Polyunsaturated Fatty Acids And Medium Chain Triglycerides , amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g (<i>Alfamino</i>)
2900P	Amino Acid Synthetic Formula Supplemented With Long Chain Polyunsaturated Fatty Acids And Medium Chain Triglycerides , amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g (<i>Alfamino</i>)
10002K	Atorvastatin (&) Ezetimibe , atorvastatin 10 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack (<i>Atozet Composite Pack 10mg + 10mg</i>)
2874G	Atorvastatin (&) Ezetimibe , atorvastatin 20 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack (<i>Atozet Composite Pack 10mg + 20mg</i>)
2821L	Atorvastatin (&) Ezetimibe , atorvastatin 40 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack (<i>Atozet Composite Pack 10mg + 40mg</i>)
10006P	Atorvastatin (&) Ezetimibe , atorvastatin 80 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack (<i>Atozet Composite Pack 10mg + 80mg</i>)
2867X	Budesonide + Eformoterol , budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 2 x 120 actuations (<i>Symbicort Rapihaler 50/3</i>)
2938P	Budesonide + Eformoterol , budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 2 x 120 actuations (<i>Symbicort Rapihaler 100/3</i>)
2866W	Budesonide + Eformoterol , budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: pressurised, 2 x 120 actuations (<i>Symbicort Rapihaler 200/6</i>)
2873F	Canagliflozin , canagliflozin 100 mg tablet, 30 (<i>Invokana</i>)
2987F	Canagliflozin , canagliflozin 300 mg tablet, 30 (<i>Invokana</i>)
2963Y	Dabrafenib , dabrafenib 50 mg capsule, 120 (<i>Tafinlar</i>)
2954L	Dabrafenib , dabrafenib 50 mg capsule, 120 (<i>Tafinlar</i>)
2846T	Dabrafenib , dabrafenib 75 mg capsule, 120 (<i>Tafinlar</i>)
10003L	Dabrafenib , dabrafenib 75 mg capsule, 120 (<i>Tafinlar</i>)
10011X	Dapagliflozin , dapagliflozin 10 mg tablet, 28 (<i>Forxiga</i>)
2896K	Dimethyl Fumarate , dimethyl fumarate 120 mg capsule, 14 (<i>Tecfidera</i>)
2943X	Dimethyl Fumarate , dimethyl fumarate 120 mg capsule, 14 (<i>Tecfidera</i>)
2966D	Dimethyl Fumarate , dimethyl fumarate 240 mg capsule, 56 (<i>Tecfidera</i>)
2818H	Everolimus , everolimus 2.5 mg tablet, 30 (<i>Afinitor</i>)
2819J	Everolimus , everolimus 5 mg tablet, 30 (<i>Afinitor</i>)
2985D	Everolimus , everolimus 10 mg tablet, 30 (<i>Afinitor</i>)
2827T	Fluticasone + Eformoterol , fluticasone propionate 50 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations (<i>flutiform 50/5</i>)
10007Q	Fluticasone + Eformoterol , fluticasone propionate 125 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations (<i>flutiform 125/5</i>)
10008R	Fluticasone + Eformoterol , fluticasone propionate 250 microgram/actuation + eformoterol fumarate dihydrate 10 microgram/actuation inhalation: pressurised, 120 actuations (<i>flutiform 250/10</i>)
10012Y	Ivabradine , ivabradine 5 mg tablet, 56 (<i>Coralan</i>)
2960T	Ivabradine , ivabradine 7.5 mg tablet, 56 (<i>Coralan</i>)
2868Y	Ivermectin , ivermectin 3 mg tablet, 4 (<i>Stromectol</i>)
2975N	Milk Powder Lactose Free Formula Predigested , milk powder lactose free formula predigested oral liquid: powder for, 900 g (<i>Karicare Aptamil Gold De-Lact</i>)
2989H	Milk Powder Lactose Free Formula Predigested , milk powder lactose free formula predigested oral liquid: powder for, 900 g (<i>Karicare Aptamil Gold De-Lact</i>)
10005N	Olmesartan + Amlodipine + Hydrochlorothiazide , olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30 (<i>Sevikar HCT 20/5/12.5</i>)
2880N	Olmesartan + Amlodipine + Hydrochlorothiazide , olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30 (<i>Sevikar HCT 40/5/12.5</i>)
2864R	Olmesartan + Amlodipine + Hydrochlorothiazide , olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 25 mg tablet, 30 (<i>Sevikar HCT 40/5/25</i>)
2836G	Olmesartan + Amlodipine + Hydrochlorothiazide , olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30 (<i>Sevikar HCT 40/10/12.5</i>)
2953K	Olmesartan + Amlodipine + Hydrochlorothiazide , olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25

	mg tablet, 30 (<i>Sevikar HCT 40/10/25</i>)
10001J	Rifaximin , rifaximin 550 mg tablet, 56 (<i>Xifaxan</i>)
10004M	Sunitinib , sunitinib 12.5 mg capsule, 28 (<i>Sutent</i>)
10009T	Sunitinib , sunitinib 12.5 mg capsule, 28 (<i>Sutent</i>)
2959R	Sunitinib , sunitinib 25 mg capsule, 28 (<i>Sutent</i>)
2842N	Sunitinib , sunitinib 25 mg capsule, 28 (<i>Sutent</i>)
2837H	Sunitinib , sunitinib 50 mg capsule, 28 (<i>Sutent</i>)
10010W	Sunitinib , sunitinib 50 mg capsule, 28 (<i>Sutent</i>)
2817G	Terbutaline , terbutaline sulfate 500 microgram/actuation inhalation: powder for, 100 actuations (<i>Bricanyl Turbuhaler</i>)
2898M	Teriflunomide , teriflunomide 14 mg tablet, 28 (<i>Aubagio</i>)
2870C	Whey Protein Formula Supplemented With Amino Acids, Long Chain Polyunsaturated Fatty Acids, Vitamins And Minerals, Low In Protein, Phosphate, Potassium And Lactose , whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 6 x 400 g cans (<i>Renastart</i>)

Addition – Brand

8295N	<i>Auro-Candesartan 4, DO</i> – Candesartan , candesartan cilexetil 4 mg tablet, 30
8296P	<i>Auro-Candesartan 8, DO</i> – Candesartan , candesartan cilexetil 8 mg tablet, 30
8297Q	<i>Auro-Candesartan 16, DO</i> – Candesartan , candesartan cilexetil 16 mg tablet, 30
8889W	<i>Auro-Candesartan 32, DO</i> – Candesartan , candesartan cilexetil 32 mg tablet, 30
1706T	<i>Carbamazepine Sandoz, SZ</i> – Carbamazepine , CARBAMAZEPINE Tablet 200 mg, 100
1724R	<i>Carbamazepine Sandoz, SZ</i> – Carbamazepine , CARBAMAZEPINE Tablet 200 mg, 100
1153Q	<i>Carbimazol ARISTO, PQ</i> – Carbimazole , carbimazole 5 mg tablet, 100
9155W	<i>Deotone 30, SZ</i> – Duloxetine , duloxetine 30 mg capsule: enteric, 28
9156X	<i>Deotone 60, SZ</i> – Duloxetine , duloxetine 60 mg capsule: enteric, 28
8243W	<i>Latanoprost Actavis, GN</i> – Latanoprost , latanoprost 0.005% eye drops, 2.5 mL
5552F	<i>Latanoprost Actavis, GN</i> – Latanoprost , latanoprost 0.005% eye drops, 2.5 mL
8612G	<i>lax-sachets, AE</i> – Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate , macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets
5389P	<i>lax-sachets, AE</i> – Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate , macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets (Palliative Care)
5390Q	<i>lax-sachets, AE</i> – Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate , macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets (Palliative Care)
1324Q	<i>Metatar, FM</i> – Metoprolol Tartrate , METOPROLOL TARTRATE Tablet 50 mg, 100 (<i>Metatar and Lopresor 50 are equivalent for the purposes of substitution</i>)
1325R	<i>Metatar, FM</i> – Metoprolol Tartrate , METOPROLOL TARTRATE Tablet 100 mg, 60 (<i>Metatar and Lopresor 100 are equivalent for the purposes of substitution</i>)
9006B	<i>PREXUM 2.5, RX</i> – Perindopril , perindopril arginine 2.5 mg tablet, 30
9007C	<i>PREXUM 5, RX</i> – Perindopril , perindopril arginine 5 mg tablet, 30
9008D	<i>PREXUM 10, RX</i> – Perindopril , perindopril arginine 10 mg tablet, 30
2845R	<i>Prexum Combi 5/1.25, RX</i> – Perindopril + Indapamide , perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30
8363E	<i>Evifyne, EL</i> – Raloxifene , raloxifene hydrochloride 60 mg tablet, 28
8363E	<i>Raloxifene GH, GQ</i> – Raloxifene , raloxifene hydrochloride 60 mg tablet, 28
1760P	<i>Roxithromycin GH, GQ</i> – Roxithromycin , roxithromycin 150 mg tablet, 10
5260W	<i>Roxithromycin GH, GQ</i> – Roxithromycin , roxithromycin 150 mg tablet, 10
8016X	<i>Roxithromycin GH, GQ</i> – Roxithromycin , roxithromycin 300 mg tablet, 5
5261X	<i>Roxithromycin GH, GQ</i> – Roxithromycin , roxithromycin 300 mg tablet, 5
9070J	<i>APO-Ziprasidone, TX</i> – Ziprasidone , ziprasidone 20 mg capsule, 60
9071K	<i>APO-Ziprasidone, TX</i> – Ziprasidone , ziprasidone 40 mg capsule, 60
9072L	<i>APO-Ziprasidone, TX</i> – Ziprasidone , ziprasidone 60 mg capsule, 60
9073M	<i>APO-Ziprasidone, TX</i> – Ziprasidone , ziprasidone 80 mg capsule, 60

Addition – Equivalence Indicator

8363E	<i>Evista, LY</i> – Raloxifene , raloxifene hydrochloride 60 mg tablet, 28
9070J	<i>Zeldox, PF</i> – Ziprasidone , ziprasidone 20 mg capsule, 60
9071K	<i>Zeldox, PF</i> – Ziprasidone , ziprasidone 40 mg capsule, 60
9072L	<i>Zeldox, PF</i> – Ziprasidone , ziprasidone 60 mg capsule, 60
9073M	<i>Zeldox, PF</i> – Ziprasidone , ziprasidone 80 mg capsule, 60

Addition – Restriction

1713E	Insulin Neutral Bovine , insulin neutral bovine 100 international units/mL injection, 1 x 10 mL vial (<i>Hypurin Neutral</i>)
1711C	Insulin Isophane Bovine , insulin isophane bovine 100 international units/mL injection, 1 x 10 mL vial (<i>Hypurin Isophane</i>)

Addition – Note

The following note now applies to the items listed below.

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5544T	Betaxolol , betaxolol 0.5% eye drops, 5 mL (<i>Betoptic, BetoQuin</i>)
5543R	Betaxolol , betaxolol 0.25% eye drops, 5 mL (<i>Betoptic S</i>)
5551E	Bimatoprost , bimatoprost 0.03% eye drops, 3 mL (<i>Lumigan</i>)
5558M	Bimatoprost + Timolol , bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL (<i>Ganfort 0.3/5</i>)
5534G	Brimonidine , brimonidine tartrate 0.2% eye drops, 5 mL (<i>Alphagan, Enidin</i>)
5563T	Brimonidine , brimonidine tartrate 0.15% eye drops, 5 mL (<i>Alphagan P 1.5</i>)
5535H	Brimonidine + Timolol , brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL (<i>Combigan</i>)
5540N	Brinzolamide , brinzolamide 1% (10 mg/mL) eye drops, 5 mL (<i>Azopt, BrinzoQuin</i>)
5562R	Brinzolamide + Timolol , brinzolamide 1% (10 mg/mL) + timolol 0.5% (5 mg/mL) eye drops, 5 mL (<i>Azarga</i>)
5541P	Dorzolamide , dorzolamide 2% (20 mg/mL) eye drops, 5 mL (<i>Trusopt</i>)
5542Q	Dorzolamide + Timolol , dorzolamide 2% + timolol 0.5% eye drops, 5 mL (<i>Cosopt</i>)
5552F	Latanoprost , latanoprost 0.005% eye drops, 2.5 mL (<i>APO-Latanoprost, Chem mart Latanoprost, Latanoprost Actavis, Latanoprost Pfizer, Latanoprost Sandoz, Terry White Chemists Latanoprost, Xalatan</i>)
5553G	Latanoprost + Timolol , latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL (<i>Latanocom, Xalacom</i>)
5536J	Pilocarpine , pilocarpine hydrochloride 1% eye drops, 15 mL (<i>Isopto Carpine</i>)
5537K	Pilocarpine , pilocarpine hydrochloride 2% eye drops, 15 mL (<i>Isopto Carpine</i>)
5538L	Pilocarpine , pilocarpine hydrochloride 4% eye drops, 15 mL (<i>Isopto Carpine</i>)
2748P	Tafluprost , tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses (<i>Saflutan</i>)
5546X	Timolol , timolol 0.1% eye gel, 5 g (<i>Nyogel</i>)
5547Y	Timolol , timolol 0.25% (2.5 mg/mL) eye drops, 5 mL (<i>Tenopt</i>)
5549C	Timolol , timolol 0.25% (2.5 mg/mL) eye drops, 2.5 mL (<i>Timoptol XE</i>)
5548B	Timolol , timolol 0.5% (5 mg/mL) eye drops, 5 mL (<i>Tenopt, Timoptol</i>)
5550D	Timolol , timolol 0.5% (5 mg/mL) eye drops, 2.5 mL (<i>Timoptol XE</i>)
5555J	Timolol + Travoprost , timolol 0.5% + travoprost 0.004% eye drops, 2.5 mL (<i>Duotrav</i>)
5554H	Travoprost , travoprost 0.004% (40 microgram/mL) eye drops, 2.5 mL (<i>Travatan</i>)

Deletions

Deletion – Item

1573T	Ketoconazole , ketoconazole 200 mg tablet, 10 (<i>Nizoral</i>)
1572R	Ketoconazole , ketoconazole 200 mg tablet, 30 (<i>Nizoral</i>)

Deletion – Brand

8179L	STADA <i>Anastrozole</i> , TD – Anastrozole , anastrozole 1 mg tablet, 30
8213G	STADA <i>Atorvastatin</i> , TD – Atorvastatin , atorvastatin 10 mg tablet, 30
9230T	STADA <i>Atorvastatin</i> , TD – Atorvastatin , atorvastatin 10 mg tablet, 30
8214H	STADA <i>Atorvastatin</i> , TD – Atorvastatin , atorvastatin 20 mg tablet, 30
9231W	STADA <i>Atorvastatin</i> , TD – Atorvastatin , atorvastatin 20 mg tablet, 30
8215J	STADA <i>Atorvastatin</i> , TD – Atorvastatin , atorvastatin 40 mg tablet, 30
9232X	STADA <i>Atorvastatin</i> , TD – Atorvastatin , atorvastatin 40 mg tablet, 30
8521L	STADA <i>Atorvastatin</i> , TD – Atorvastatin , atorvastatin 80 mg tablet, 30
9233Y	STADA <i>Atorvastatin</i> , TD – Atorvastatin , atorvastatin 80 mg tablet, 30
8295N	STADA <i>Candesartan</i> , TD – Candesartan , candesartan cilexetil 4 mg tablet, 30
8296P	STADA <i>Candesartan</i> , TD – Candesartan , candesartan cilexetil 8 mg tablet, 30
8297Q	STADA <i>Candesartan</i> , TD – Candesartan , candesartan cilexetil 16 mg tablet, 30
8889W	STADA <i>Candesartan</i> , TD – Candesartan , candesartan cilexetil 32 mg tablet, 30
8504N	STADA <i>Candesartan HCT 16/12.5</i> , TD – Candesartan + Hydrochlorothiazide , candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
9314F	STADA <i>Candesartan HCT 32/12.5</i> , TD – Candesartan + Hydrochlorothiazide , candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
9315G	STADA <i>Candesartan HCT 32/25</i> , TD – Candesartan + Hydrochlorothiazide , candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
9354H	STADA <i>Clopidogrel</i> , TD – Clopidogrel , clopidogrel 75 mg tablet, 28
2532G	STADA <i>Donepezil</i> , TD – Donepezil , donepezil hydrochloride 5 mg tablet, 28
8495D	STADA <i>Donepezil</i> , TD – Donepezil , donepezil hydrochloride 5 mg tablet, 28
2479L	STADA <i>Donepezil</i> , TD – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8496E	STADA <i>Donepezil</i> , TD – Donepezil , donepezil hydrochloride 10 mg tablet, 28
8246B	STADA <i>Irbesartan</i> , TD – Irbesartan , irbesartan 75 mg tablet, 30

8247C	STADA Irbesartan, TD – Irbesartan , irbesartan 150 mg tablet, 30
8248D	STADA Irbesartan, TD – Irbesartan , irbesartan 300 mg tablet, 30
8404H	STADA Irbesartan HCT 150/12.5, TD – Irbesartan + Hydrochlorothiazide , irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30
8405J	STADA Irbesartan HCT 300/12.5, TD – Irbesartan + Hydrochlorothiazide , irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30
2136K	STADA Irbesartan HCT 300/25, TD – Irbesartan + Hydrochlorothiazide , irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30
8245Y	STADA Letrozole, TD – Letrozole , letrozole 2.5 mg tablet, 30
1324Q	APO-Metoprolol, TX – Metoprolol Tartrate , METOPROLOL TARTRATE Tablet 50 mg, 100
1325R	APO-Metoprolol, TX – Metoprolol Tartrate , METOPROLOL TARTRATE Tablet 100 mg, 60
1024X	STADA Olanzapine, TD – Olanzapine , olanzapine 2.5 mg tablet, 28
1037N	STADA Olanzapine, TD – Olanzapine , olanzapine 5 mg tablet, 28
1041T	STADA Olanzapine, TD – Olanzapine , olanzapine 7.5 mg tablet, 28
1042W	STADA Olanzapine, TD – Olanzapine , olanzapine 10 mg tablet, 28
3381Y	STADA Olanzapine ODT, TD – Olanzapine , OLANZAPINE Tablet 5 mg (orally disintegrating), 28
3382B	STADA Olanzapine ODT, TD – Olanzapine , OLANZAPINE Tablet 10 mg (orally disintegrating), 28
8007K	STADA Pantoprazole, TD – Pantoprazole , pantoprazole 40 mg tablet: enteric, 30
8008L	STADA Pantoprazole, TD – Pantoprazole , pantoprazole 40 mg tablet: enteric, 30
8456C	STADA Quetiapine, TD – Quetiapine , quetiapine 25 mg tablet, 60
8457D	STADA Quetiapine, TD – Quetiapine , quetiapine 100 mg tablet, 90
8458E	STADA Quetiapine, TD – Quetiapine , quetiapine 200 mg tablet, 60
8580N	STADA Quetiapine, TD – Quetiapine , quetiapine 300 mg tablet, 60
8508T	STADA Rabeprazole, TD – Rabeprazole , rabeprazole sodium 20 mg tablet: enteric, 30 tablets
8509W	STADA Rabeprazole, TD – Rabeprazole , rabeprazole sodium 20 mg tablet: enteric, 30 tablets
8301X	STADA Venlafaxine-SR, TD – Venlafaxine , venlafaxine 75 mg capsule: modified release, 28 capsules
8302Y	STADA Venlafaxine-SR, TD – Venlafaxine , venlafaxine 150 mg capsule: modified release, 28 capsules

Deletion – Equivalence Indicator

1024X	Olanzapine generichealth 2.5, GQ – Olanzapine , olanzapine 2.5 mg tablet, 28
1037N	Olanzapine generichealth 5, GQ – Olanzapine , olanzapine 5 mg tablet, 28
1041T	Olanzapine generichealth 7.5, GQ – Olanzapine , olanzapine 7.5 mg tablet, 28
1042W	Olanzapine generichealth 10, GQ – Olanzapine , olanzapine 10 mg tablet, 28

Alterations

Alteration – Brand Name

From:	
1784X	DBL Ceftriaxone, HH – Ceftriaxone , ceftriaxone 1 g injection, 1 x 1 g vial
To:	
1784X	Hospira Ceftriaxone, HH – Ceftriaxone , ceftriaxone 1 g injection, 1 x 1 g vial
From:	
1785Y	DBL Ceftriaxone, HH – Ceftriaxone , ceftriaxone 2 g injection, 1 x 2 g vial
To:	
1785Y	Hospira Ceftriaxone, HH – Ceftriaxone , ceftriaxone 2 g injection, 1 x 2 g vial
From:	
8318T	Clarithexal, SZ – Clarithromycin , clarithromycin 250 mg tablet, 14
To:	
8318T	Clarithromycin Sandoz, SZ – Clarithromycin , clarithromycin 250 mg tablet, 14
From:	
9031H	Daktarin, JT – Miconazole , miconazole 2% (20 mg/mL) lotion, 30 mL
To:	
9031H	Daktarin Tincture, JT – Miconazole , miconazole 2% (20 mg/mL) lotion, 30 mL

Alteration – Number of Repeats

		From	To
3414Q	Nicotine , nicotine 21 mg/24 hours patch, 28 (<i>Nicotinell Step 1</i>)	0	2
5572G	Nicotine , nicotine 14 mg/24 hours patch, 28 (<i>Nicotinell Step 2</i>)	0	2
5573H	Nicotine , nicotine 7 mg/24 hours patch, 28 (<i>Nicotinell Step 3</i>)	0	2

Alteration – Restriction

5457F	Denosumab , denosumab 60 mg/mL injection, 1 x 1 mL syringe (<i>Prolia</i>)
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5443L	Imatinib , imatinib 100 mg tablet, 60 (<i>Glivec</i>)
5444M	Imatinib , imatinib 400 mg tablet, 30 (<i>Glivec</i>)
8359Y	Ivermectin , ivermectin 3 mg tablet, 4 (<i>Stromectol</i>)
3387G	Linagliptin , linagliptin 5 mg tablet, 30 (<i>Trajenta</i>)
9198D	Nicotine , NICOTINE Transdermal patch releasing approximately 15 mg per 16 hours, 28 (<i>Nicorette Patch</i>)
5465P	Nicotine , nicotine 21 mg/24 hours patch, 28 (<i>Nicabate P</i>)
3414Q	Nicotine , nicotine 21 mg/24 hours patch, 28 (<i>Nicotinell Step 1</i>)
5571F	Nicotine , nicotine 21 mg/24 hours patch, 28 (<i>Nicotinell Step 1</i>)
5572G	Nicotine , nicotine 14 mg/24 hours patch, 28 (<i>Nicotinell Step 2</i>)
5573H	Nicotine , nicotine 7 mg/24 hours patch, 28 (<i>Nicotinell Step 3</i>)
8983T	Saxagliptin , saxagliptin 5 mg tablet, 28 (<i>Onglyza</i>)
9180E	Sitagliptin , sitagliptin 25 mg tablet, 28 (<i>Januvia</i>)
9181F	Sitagliptin , sitagliptin 50 mg tablet, 28 (<i>Januvia</i>)
9182G	Sitagliptin , sitagliptin 100 mg tablet, 28 (<i>Januvia</i>)
9449H	Sitagliptin + Metformin , sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56 (<i>Janumet</i>)
9450J	Sitagliptin + Metformin , sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56 (<i>Janumet</i>)
9451K	Sitagliptin + Metformin , sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56 (<i>Janumet</i>)
3415R	Vildagliptin , vildagliptin 50 mg tablet, 60 (<i>Galvus</i>)
5474D	Vildagliptin + Metformin , vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60 (<i>Galvumet 50/500</i>)
5475E	Vildagliptin + Metformin , vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60 (<i>Galvumet 50/850</i>)
5476F	Vildagliptin + Metformin , vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60 (<i>Galvumet 50/1000</i>)

Advance Notices

Advance Notices – Deletion of Item

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 January 2014:

8373Q	Leflunomide , leflunomide 100 mg tablet [3 tablets] (&) leflunomide 20 mg tablet [30 tablets], 33 (<i>Arava</i>)
2350Q	Milk Powder Lactose Free Formula Predigested , milk powder lactose free formula predigested oral liquid: powder for, 900 g (<i>Karicare Aptamil De-Lact</i>)
2349P	Milk Powder Lactose Free Formula Predigested , milk powder lactose free formula predigested oral liquid: powder for, 900 g (<i>Karicare Aptamil De-Lact</i>)
8629E	Triglycerides Medium Chain Formula , triglycerides medium chain formula oral liquid: powder for, 420 g (<i>Caprilon</i>)

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 March 2014:

5455D	Degarelix , degarelix 80 mg injection: subcutaneous infusion [1 x 80 mg vial] (&) inert substance diluent [1 x 4.2 mL vial], 1 pack (<i>Firmagon 80mg</i>)
5456E	Degarelix , degarelix 120 mg injection: subcutaneous infusion [2 x 120 mg vials] (&) inert substance diluent [2 x 3 mL vials], 1 pack (<i>Firmagon 120mg</i>)

The following item will be deleted from the Schedule of Pharmaceutical Benefits on 1 April 2014:

1252X	Terbutaline , terbutaline sulfate 500 microgram/actuation inhalation: powder for, 200 actuations (<i>Bricanyl Turbuhaler</i>)
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Advance Notices – Deletion of Brand

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 February 2014:

2130D	<i>Xanax, PF</i> – Alprazolam , alprazolam 250 microgram tablet, 50
2131E	<i>Xanax, PF</i> – Alprazolam , alprazolam 500 microgram tablet, 50
2132F	<i>Xanax, PF</i> – Alprazolam , alprazolam 1 mg tablet, 50
8118G	<i>Xanax Tri-Score, PF</i> – Alprazolam , alprazolam 2 mg tablet, 50

SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

Additions

Addition – Item

10000H **Darunavir**, darunavir 800 mg tablet, 30 (*Prezista*) **(Private)**
 2980W **Darunavir**, darunavir 800 mg tablet, 30 (*Prezista*) **(Public)**

Advance Notices

Advance Notices – Deletion of Item

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 January 2014:

6256G **Ganciclovir**, ganciclovir 4.5 mg implant, 1 (*Vitrasert*)**(Private)**
 5748M **Ganciclovir**, ganciclovir 4.5 mg implant, 1 (*Vitrasert*)**(Public)**

REPATRIATION PHARMACEUTICAL BENEFITS

Deletions

Deletion – Item

4191N **Diphemanil**, diphemanil methylsulfate 2% (20 mg/g) powder: dusting, 50 g (*Prantal*)

Alterations

Alteration – Brand Name

From:

4341L *Daktarin, JT* – **Miconazole**, miconazole 2% (20 mg/mL) lotion, 30 mL

To:

4341L *Daktarin Tincture, JT* – **Miconazole**, miconazole 2% (20 mg/mL) lotion, 30 mL

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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ALOGLIPTIN

Authority required (STREAMLINED)

4349

Diabetes mellitus type 2

The Clinical criteria is:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND the Clinical criteria is:

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with alogliptin.

Note

Alogliptin is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

2944Y NP	alogliptin 6.25 mg tablet, 28	1	5	..	59.07	36.10	Nesina	TK
2933J NP	alogliptin 12.5 mg tablet, 28	1	5	..	59.07	36.10	Nesina	TK
2986E NP	alogliptin 25 mg tablet, 28	1	5	..	59.07	36.10	Nesina	TK

AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Authority required

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

The Treatment criteria is:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist,

AND the Clinical criteria is:

The condition must not be isolated infant colic or reflux,

AND the Clinical criteria is:

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula,

AND the Population criteria is:

Patient must be up to the age of 24 months.

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The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

The Treatment criteria is:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist,

AND the Clinical criteria is:

The condition must not be isolated infant colic or reflux,

AND the Population criteria is:

Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Initial treatment for up to 6 months

The Treatment criteria is:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist,

AND the Clinical criteria is:

The condition must not be isolated infant colic or reflux,

AND the Population criteria is:

Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Initial treatment for up to 6 months

The Treatment criteria is:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or in consultation with a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist,

AND the Clinical criteria is:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides),

AND the Population criteria is:

Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority 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.

2928D NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g	8	5	..	*368.07	36.10	Alfamino	NT
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AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES

Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

GENERAL PHARMACEUTICAL BENEFITS

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The Treatment criteria is:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have an appointment to be assessed by one of these specialists,

AND the Clinical criteria is:

The condition must not be isolated infant colic or reflux,

AND the Clinical criteria is:

Patient must be intolerant to both soy protein and protein hydrolysate formulae, as demonstrated when the child has failed to respond to a strict cows' milk protein free and strict soy protein free diet with a protein hydrolysate (with or without medium chain triglycerides) as the principal formula,

AND the Population criteria is:

Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

The Treatment criteria is:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist, or have been assessed at least once or have an appointment to be assessed by one of these specialists,

AND the Clinical criteria is:

The condition must not be isolated infant colic or reflux,

AND the Clinical criteria is:

Patient must have had failure to thrive prior to commencement with initial treatment,

AND the Population criteria is:

Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Combined intolerance to cows' milk protein, soy protein and protein hydrolysate formulae

Treatment Phase: Continuing treatment

The Treatment criteria is:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist at intervals not greater than 12 months,

AND the Clinical criteria is:

The condition must not be isolated infant colic or reflux,

AND the Population criteria is:

Patient must be older than 24 months of age.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Authority required

Cows' milk anaphylaxis

The Treatment criteria is:

Must be treated by a specialist allergist or clinical immunologist, or in consultation with a specialist allergist or clinical immunologist,

AND the Population criteria is:

Patient must be up to the age of 24 months.

Anaphylaxis is defined as a severe and/or potentially life threatening allergic reaction.

The name of the specialist and the date of birth of the patient must be included in the authority application.

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Authority required

Proven combined immunoglobulin E (IgE) mediated allergy to cows' milk protein and soy protein

Treatment Phase: Continuing treatment

The Treatment criteria is:

Must be treated by a specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist,

AND the Clinical criteria is:

Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment,

AND the Population criteria is:

Patient must be up to the age of 24 months.

The name of the specialist and the date of birth of the patient must be included in the authority application.

Note

Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.

2900P NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g	8	5	..	*368.07	36.10	Alfamino	NT
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ATORVASTATIN (&) EZETIMIBE

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which

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shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a

GENERAL PHARMACEUTICAL BENEFITS

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maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

The Clinical criteria is:

Patient must have homozygous familial hypercholesterolaemia,

AND the Clinical criteria is:

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

Authority required (STREAMLINED)

4353

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	Hypercholesterolaemia						
	The Clinical criteria is:						
	Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs),						
	AND the Clinical criteria is:						
	Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the atorvastatin dose.						
	A clinically important product-related adverse event is defined as follows:						
	(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or						
	(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or						
	(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.						
	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.						
10002K NP	atorvastatin 10 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack	‡1	5	..	82.18	36.10	Atozet Composite Pack 10mg + 10mg

ATORVASTATIN (&) EZETIMIBE

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol

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Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at

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any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

The Clinical criteria is:

The treatment must be in conjunction with dietary therapy and exercise,

AND the Clinical criteria is:

Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin),

AND the Clinical criteria is:

Patient must have hypertension.

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

The Clinical criteria is:

Patient must have homozygous familial hypercholesterolaemia,

AND the Clinical criteria is:

Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

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.

2874G	atorvastatin 20 mg tablet [30] (&	#1	5	..	87.41	36.10	Atozet Composite Pack	MK
NP	ezetimibe 10 mg tablet [30], 1 pack						10mg + 20mg	

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2821L NP	atorvastatin 40 mg tablet [30] (& ezetimibe 10 mg tablet [30], 1 pack	1	5	..	94.04	36.10	Atozet Composite Pack 10mg + 40mg	MK
10006P NP	atorvastatin 80 mg tablet [30] (& ezetimibe 10 mg tablet [30], 1 pack	1	5	..	103.85	36.10	Atozet Composite Pack 10mg + 80mg	MK

BETAXOLOL

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5544T OP	betaxolol 0.5% eye drops, 5 mL	1	5	..	14.98	16.11	^a BetoQuin	IQ
				^b 2.08	17.06	16.11	^a Betoptic	AQ
5543R OP	betaxolol 0.25% eye drops, 5 mL	1	5	..	14.98	16.11	Betoptic S	AQ

BIMATOPROST

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5551E OP	bimatoprost 0.03% eye drops, 3 mL	1	5	..	42.35	36.10	Lumigan	AG
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BIMATOPROST + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

The Clinical criteria is:

The condition must have been inadequately controlled with monotherapy,

AND the Clinical criteria is:

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5558M OP	bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL	1	5	..	46.81	36.10	Ganfort 0.3/5	AG
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BRIMONIDINE

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5534G OP	brimonidine tartrate 0.2% eye drops, 5 mL	1	5	..	20.35	21.48	^a Enidin	PE
				^b 1.63	21.98	21.48	^a Alphagan	AG
5563T OP	brimonidine tartrate 0.15% eye drops, 5 mL	1	5	..	20.35	21.48	Alphagan P 1.5	AG

BRIMONIDINE + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

The Clinical criteria is:

The condition must have been inadequately controlled with monotherapy,

AND the Clinical criteria is:

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an

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agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5535H OP	brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL	1	5	..	26.24	27.37	Combigan	AG
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BRINZOLAMIDE

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5540N OP	brinzolamide 1% (10 mg/mL) eye drops, 5 mL	1	5	..	22.98	24.11	^a BrinzoQuin	IQ
				^b 1.18	24.16	24.11	^a Azopt	AQ

BRINZOLAMIDE + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

The Clinical criteria is:

The condition must have been inadequately controlled with monotherapy,

AND the Clinical criteria is:

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5562R OP	brinzolamide 1% (10 mg/mL) + timolol 0.5% (5 mg/mL) eye drops, 5 mL	1	5	..	27.09	28.22	Azarga	AQ
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BUDESONIDE + EFORMOTEROL

Restricted benefit

Asthma

The Clinical criteria is:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids and have been stabilised on concomitant inhaled eformoterol fumarate and budesonide.

Note

Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

The Clinical criteria is:

Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy,

AND the Clinical criteria is:

Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy.

Note

Budesonide with eformoterol fumarate dihydrate is not indicated for the initiation of bronchodilator therapy in COPD.

2866W NP	budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: pressurised, 2 x 120 actuations	1	5	..	90.76	36.10	Symbicort Rapihaler 200/6	AP
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BUDESONIDE + EFORMOTEROL

Restricted benefit

Asthma

The Clinical criteria is:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids and have been stabilised on concomitant inhaled eformoterol fumarate and budesonide; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with oral or inhaled corticosteroids and require single maintenance and reliever therapy; OR

Patient must have experienced frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and long acting beta-2 agonist.

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2867X NP	budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 2 x 120 actuations	1	5	..	54.68	36.10	Symbicort Rapihaler 50/3	AP
2938P NP	budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 2 x 120 actuations	1	5	..	58.98	36.10	Symbicort Rapihaler 100/3	AP

CANAGLIFLOZIN

Authority required

Diabetes mellitus type 2

The Clinical criteria is:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND the Clinical criteria is:

The condition must not be able to be adequately controlled by treatment with metformin and a sulfonylurea,

AND the Clinical criteria is:

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co- transporter 2 (SGLT2) inhibitor; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

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.

Note

Canagliflozin is not PBS subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with an insulin, a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

2873F NP	canagliflozin 100 mg tablet, 30	1	5	..	96.48	36.10	Invokana	JC
2987F NP	canagliflozin 300 mg tablet, 30	1	5	..	96.48	36.10	Invokana	JC

DABRAFENIB

Authority required

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

The Clinical criteria is:

The treatment must be the sole PBS-subsidised therapy for this condition,

AND the Clinical criteria is:

The condition must be positive for a BRAF V600 mutation,

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AND the Clinical criteria is:

The condition must not have been treated previously with PBS subsidised therapy; OR

Patient must have developed intolerance to another BRAF inhibitor of a severity necessitating permanent treatment withdrawal,

AND the Clinical criteria is:

Patient must have a WHO performance status of 2 or less.

Note

A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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.

2963Y	dabrafenib 50 mg capsule, 120	1	3	..	5888.02	36.10	Tafinlar	GK
2846T	dabrafenib 75 mg capsule, 120	1	3	..	8758.74	36.10	Tafinlar	GK

DABRAFENIB

Authority required

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

The Clinical criteria is:

The treatment must be the sole PBS-subsidised therapy for this condition,

AND the Clinical criteria is:

Patient must have previously been issued with an authority prescription for this drug,

AND the Clinical criteria is:

Patient must have stable or responding disease.

Note

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

Note

A patient who has had progressive disease when treated with another BRAF inhibitor is not eligible to receive PBS-subsidised treatment with this drug.

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.

2954L	dabrafenib 50 mg capsule, 120	1	5	..	5888.02	36.10	Tafinlar	GK
10003L	dabrafenib 75 mg capsule, 120	1	5	..	8758.74	36.10	Tafinlar	GK

DAPAGLIFLOZIN

Authority required

Diabetes mellitus type 2

The Clinical criteria is:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND the Clinical criteria is:

The condition must not be able to be adequately controlled by treatment with metformin and a sulfonylurea,

AND the Clinical criteria is:

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Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co- transporter 2 (SGLT2) inhibitor; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

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.

Note

Dapagliflozin is not PBS subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with an insulin, a thiazolidinedione (glitazone), a dipeptidyl peptidase 4 inhibitor (gliptin) or a glucagon-like peptide-1.

10011X NP	dapagliflozin 10 mg tablet, 28	1	5	..	90.27	36.10	Forxiga	BQ
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DENOSUMAB

Authority required (STREAMLINED)

4314

Osteoporosis

The Population criteria is:

Patient must be aged 70 years or older,

AND the Clinical criteria is:

Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less,

AND the Clinical criteria is:

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated.

Authority required (STREAMLINED)

4347

Established osteoporosis

The Clinical criteria is:

Patient must have fracture due to minimal trauma,

AND the Clinical criteria is:

Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition.

The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated.

A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Note

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	Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, denosumab, raloxifene hydrochloride, strontium ranelate and zoledronic acid.							
	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.							
5457F NP	denosumab 60 mg/mL injection, 1 x 1 mL syringe	1	298.90	36.10	Prolia	AN
	DIMETHYL FUMARATE							
	Authority required							
	Multiple sclerosis							
	Treatment Phase: Initial treatment							
	The Clinical criteria is:							
	The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR							
	The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,							
	AND the Clinical criteria is:							
	The treatment must be as monotherapy,							
	AND the Clinical criteria is:							
	Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years; OR							
	Patient must have been receiving treatment with this drug prior to 1 December 2013,							
	AND the Clinical criteria is:							
	Patient must be ambulatory (without assistance or support).							
	Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority 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.							
2896K	dimethyl fumarate 120 mg capsule, 14	1	491.18	36.10	Tecfidera	BD
	DIMETHYL FUMARATE							
	Authority required							
	Multiple sclerosis							
	Treatment Phase: Continuing treatment							
	The Clinical criteria is:							
	The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR							
	The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,							
	AND the Clinical criteria is:							
	The treatment must be as monotherapy,							
	AND the Clinical criteria is:							
	Patient must have previously been issued with an authority prescription for this drug,							
	AND the Clinical criteria is:							
	Patient must not show continuing progression of disability while on treatment with this drug.							
	Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.							
	Note							
	Special Pricing Arrangements apply.							
2943X	dimethyl fumarate 120 mg capsule, 14	1	491.18	36.10	Tecfidera	BD
	DIMETHYL FUMARATE							

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	<u>Authority required</u>						
	Multiple sclerosis						
	Treatment Phase: Continuing treatment						
	The Clinical criteria is:						
	The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR						
	The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,						
	AND the Clinical criteria is:						
	The treatment must be as monotherapy,						
	AND the Clinical criteria is:						
	Patient must have previously been issued with an authority prescription for this drug,						
	AND the Clinical criteria is:						
	Patient must not show continuing progression of disability while on treatment with this drug.						
	Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.						
	<u>Note</u>						
	No increase in the maximum quantity or number of units may be authorised.						
	<u>Note</u>						
	No increase in the maximum number of repeats may be authorised.						
	<u>Note</u>						
	Special Pricing Arrangements apply.						
2966D	dimethyl fumarate 240 mg capsule, 56	1	5	..	1879.87	36.10	Tecfidera BD
	DORZOLAMIDE						
	<u>Note</u>						
	Shared Care Model:						
	For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.						
5541P OP	dorzolamide 2% (20 mg/mL) eye drops, 5 mL	£1	5	..	21.50	22.63	Trusopt MK
	DORZOLAMIDE + TIMOLOL						
	<u>Restricted benefit</u>						
	Elevated intra-ocular pressure						
	The Clinical criteria is:						
	The condition must have been inadequately controlled with monotherapy,						
	AND the Clinical criteria is:						
	Patient must have open-angle glaucoma; OR						
	Patient must have ocular hypertension.						
	<u>Note</u>						
	Shared Care Model:						
	For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.						
5542Q OP	dorzolamide 2% + timolol 0.5% eye drops, 5 mL	£1	5	..	27.39	28.52	Cosopt MK
	EVEROLIMUS						
	<u>Authority required</u>						
	Tuberous sclerosis complex (TSC)						
	Treatment Phase: Initial treatment						
	The Clinical criteria is:						
	The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR						
	The condition must be visceral tumours associated with TSC,						
	AND the Clinical criteria is:						
	The treatment must be the sole PBS-subsidised therapy for this condition,						
	AND the Clinical criteria is:						

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Patient must not be a candidate for curative surgical resection.							
	Authority required							
	Tuberous sclerosis complex (TSC)							
	Treatment Phase: Continuing treatment							
	The Clinical criteria is:							
	The condition must be subependymal giant cell astrocytomas (SEGAs) associated with TSC; OR							
	The condition must be visceral tumours associated with TSC,							
	AND the Clinical criteria is:							
	The treatment must be the sole PBS-subsidised therapy for this condition,							
	AND the Clinical criteria is:							
	Patient must have previously been treated with PBS-subsidised everolimus for this condition,							
	AND the Clinical criteria is:							
	Patient must have demonstrated a response to prior treatment.							
	Note							
	Special Pricing Arrangements apply.							
2818H	everolimus 2.5 mg tablet, 30	1	5	..	1483.37	36.10	Afinitor	NV
2819J	everolimus 5 mg tablet, 30	1	5	..	2846.57	36.10	Afinitor	NV
2985D	everolimus 10 mg tablet, 30	1	5	..	5546.57	36.10	Afinitor	NV
	FLUTICASONE + EFORMOTEROL							
	Restricted benefit							
	Asthma							
	The Clinical criteria is:							
	Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.							
	Note							
	Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.							
	Note							
	Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.							
2827T NP	fluticasone propionate 50 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations	\$1	5	..	45.83	36.10	flutiform 50/5	MF
10007Q NP	fluticasone propionate 125 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations	\$1	5	..	56.58	36.10	flutiform 125/5	MF
10008R NP	fluticasone propionate 250 microgram/actuation + eformoterol fumarate dihydrate 10 microgram/actuation inhalation: pressurised, 120 actuations	\$1	5	..	78.65	36.10	flutiform 250/10	MF
	IMATINIB							
	Authority required							
	Gastrointestinal stromal tumour							
	Treatment Phase: Initial treatment							
	The Clinical criteria is:							
	The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST),							
	AND the Clinical criteria is:							
	Patient must be at high risk of recurrence following complete surgical resection of primary GIST,							
	AND the Clinical criteria is:							
	The condition must be histologically confirmed by the detection of CD117 on immunohistochemical staining,							
	AND the Clinical criteria is:							
	The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy).							
	Applications for authorisation of initial treatment must be in writing and must include:							

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	<p>(1) a completed authority prescription form; and</p> <p>(2) a completed Imatinib Mesylate (Glivec) PBS Authority Application for Use in Adjuvant Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form which includes the following:</p> <p>(i) a copy of a pathology report from an Approved Pathology Authority supporting the diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining; and</p> <p>(ii) a copy of the pathology report must include the size and mitotic rate of the tumour, and the date of tumour resection must be documented, which must not be more than 3 months prior to the date of this application.</p> <p>High risk of recurrence is defined as:</p> <p>Primary GIST greater than 5 cm with a mitotic count of greater than 5/50 high power fields (HPF); or</p> <p>Primary GIST greater than 10 cm with any mitotic rate; or</p> <p>Primary GIST with a mitotic count of greater than 10/50 HPF.</p> <p>Note</p> <p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au</p> <p>Applications for authority to prescribe should be forwarded to:</p> <p>Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001</p> <p>Note</p> <p>Any queries concerning patients who are enrolled on the Imatinib Compassionate Program may be directed to the Department of Human Services on 1800 700 270.</p> <p>Authority required</p> <p>Gastrointestinal stromal tumour</p> <p>Treatment Phase: Continuing treatment</p> <p>The Clinical criteria is:</p> <p>The treatment must be adjuvant to complete surgical resection of primary gastrointestinal stromal tumour (GIST),</p> <p>AND the Clinical criteria is:</p> <p>Patient must be at high risk of recurrence following complete surgical resection of primary GIST,</p> <p>AND the Clinical criteria is:</p> <p>The treatment must not exceed a dose of 400 mg per day for a period of 36 months in total (initial plus continuing therapy),</p> <p>AND the Clinical criteria is:</p> <p>Patient must have previously been issued with an authority prescription for imatinib for adjuvant treatment following complete resection of primary GIST.</p> <p>Applications for continuing therapy may be made by telephone.</p> <p>Note</p> <p>Authority approval for continuing treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Note</p> <p>Written applications for authority to prescribe should be forwarded to:</p> <p>Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 GPO Box 9826 HOBART TAS 7001</p>							
5443L	imatinib 100 mg tablet, 60	1	5	..	1963.08	36.10	Glivec	NV
5444M	imatinib 400 mg tablet, 30	1	5	..	3779.58	36.10	Glivec	NV

INSULIN ISOPHANE BOVINE

Authority required

Diabetes mellitus

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
The Clinical criteria is:								
Patient must be intolerant to human insulin.								
1711C NP	insulin isophane bovine 100 international units/mL injection, 1 x 10 mL vial	5	2	..	*400.93	36.10	Hypurin Isophane	AS
INSULIN NEUTRAL BOVINE								
<u>Authority required</u>								
Diabetes mellitus								
The Clinical criteria is:								
Patient must be intolerant to human insulin.								
1713E NP	insulin neutral bovine 100 international units/mL injection, 1 x 10 mL vial	5	2	..	*400.93	36.10	Hypurin Neutral	AS
IVABRADINE								
<u>Authority required</u>								
Chronic heart failure								
The Clinical criteria is:								
Patient must be symptomatic with NYHA classes II or III,								
AND the Clinical criteria is:								
Patient must be in sinus rhythm,								
AND the Clinical criteria is:								
Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%,								
AND the Clinical criteria is:								
Patient must have a resting heart rate at or above 77 bpm at the time ivabradine treatment is initiated,								
AND the Clinical criteria is:								
Patient must receive concomitant optimal standard chronic heart failure treatment, which must include the maximum tolerated dose of a beta-blocker, unless contraindicated or not tolerated.								
Resting heart rate should be measured by ECG after 5 minutes rest.								
The ECG result must be documented in the patient's medical records when treatment is initiated.								
<u>Note</u>								
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.								
10012Y NP	ivabradine 5 mg tablet, 56	1	5	..	56.31	36.10	Coralan	SE
2960T NP	ivabradine 7.5 mg tablet, 56	1	5	..	56.31	36.10	Coralan	SE
IVERMECTIN								
<u>Authority required (STREAMLINED)</u>								
4328								
Strongyloidiasis								
2868Y NP	ivermectin 3 mg tablet, 4	2	2	..	*54.41	36.10	Stromectol	MK
IVERMECTIN								
<u>Authority required (STREAMLINED)</u>								
4319								
Onchocerciasis								
8359Y NP	ivermectin 3 mg tablet, 4	1	31.52	32.65	Stromectol	MK
LATANOPROST								
<u>Note</u>								
Shared Care Model:								
For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.								
5552F OP	latanoprost 0.005% eye drops, 2.5 mL	1	5	..	36.78	36.10	^a APO-Latanoprost	TX
							^a Chem mart Latanoprost	CH

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							Latanoprost Actavis	GN
							Latanoprost Pfizer	FZ
							Latanoprost Sandoz	SZ
							Terry White Chemists Latanoprost	TW
							Xalatan	PF

LATANOPROST + TIMOLOL

Restricted benefit

Elevated intra-ocular pressure

The Clinical criteria is:

The condition must have been inadequately controlled with monotherapy,

AND the Clinical criteria is:

Patient must have open-angle glaucoma; OR

Patient must have ocular hypertension.

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5553G OP	latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL	‡1	5	..	41.08	36.10	^a Latanocom	FZ
							^a Xalacom	PF

LINAGLIPTIN

Authority required (STREAMLINED)

4350

Diabetes mellitus type 2

The Clinical criteria is:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND the Clinical criteria is:

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR

Patient must not have tolerated a combination of metformin and a sulfonylurea,

AND the Clinical criteria is:

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note

This drug is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

3387G NP	linagliptin 5 mg tablet, 30	1	5	..	96.82	36.10	Trajenta	BY
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MILK POWDER LACTOSE FREE FORMULA PREDIGESTED

Authority required

Acute lactose intolerance

The Population criteria is:

Patient must be up to the age of 12 months.

The date of birth of the patient must be included in the authority 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

No more than 1 application per patient will be authorised.

2975N NP	milk powder lactose free formula predigested oral liquid: powder for, 900 g	5	*95.63	36.10	Karicare Aptamil Gold De-Lact	NU
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MILK POWDER LACTOSE FREE FORMULA PREDIGESTED

Authority required

Chronic lactose intolerance

The Population criteria is:

Patient must be up to the age of 12 months,

AND the Clinical criteria is:

The condition must be proven to be lactose intolerance.

Lactose intolerance must have been proven by either:

- (a) relief of symptoms on supervised withdrawal of lactose from the diet for 3 or 4 days and subsequent re-emergence of symptoms on rechallenge with lactose containing formulae or milk or food; or
- (b) not less than 0.5% reducing substance in stool exudate tested with copper sulfate diagnostic compound tablet; or
- (c) hydrogen breath test.

The date of birth of the patient must be included in the authority 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.

2989H NP	milk powder lactose free formula predigested oral liquid: powder for, 900 g	5	5	..	*95.63	36.10	Karicare Aptamil Gold De-Lact	NU
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NICOTINE

Authority required (STREAMLINED)

4344

Nicotine dependence

The Population criteria is:

Patient must be an Aboriginal or a Torres Strait Islander person,

AND the Clinical criteria is:

The treatment must be the sole PBS-subsidised therapy for this condition.

Note

Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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Benefit is improved if used in conjunction with a comprehensive support and counselling program.

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.

Authority required (STREAMLINED)

4348

Nicotine dependence

The Clinical criteria is:

The treatment must be the sole PBS-subsidised therapy for this condition,

AND the Clinical criteria is:

Patient must have indicated they are ready to cease smoking,

AND the Clinical criteria is:

Patient must have entered a comprehensive support and counselling program,

AND the Clinical criteria is:

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

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.

Authority required (STREAMLINED)

4307

Nicotine dependence

The Clinical criteria is:

The treatment must be the sole PBS-subsidised therapy for this condition,

AND the Clinical criteria is:

Patient must have indicated they are ready to cease smoking,

AND the Clinical criteria is:

Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written,

AND the Clinical criteria is:

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.

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.

9198D NP	NICOTINE Transdermal patch releasing approximately 15 mg per 16 hours, 28	1	2	..	55.43	36.10	Nicorette Patch	JT
5465P NP	nicotine 21 mg/24 hours patch, 28	1	2	..	55.43	36.10	Nicabate P	GC

NICOTINE

Authority required (STREAMLINED)

4348

Nicotine dependence

The Clinical criteria is:

The treatment must be the sole PBS-subsidised therapy for this condition,

AND the Clinical criteria is:

Patient must have indicated they are ready to cease smoking,

AND the Clinical criteria is:

Patient must have entered a comprehensive support and counselling program,

AND the Clinical criteria is:

Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.								
<u>Authority required (STREAMLINED)</u>								
4307								
Nicotine dependence								
The Clinical criteria is:								
The treatment must be the sole PBS-subsidised therapy for this condition,								
AND the Clinical criteria is:								
Patient must have indicated they are ready to cease smoking,								
AND the Clinical criteria is:								
Patient must be entering a comprehensive support and counselling program during the consultation at which this prescription is written,								
AND the Clinical criteria is:								
Patient must not receive more than 12 weeks of PBS-subsidised nicotine replacement therapy per 12-month period.								
Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated.								
<u>Note</u>								
No increase in the maximum quantity or number of units may be authorised.								
<u>Note</u>								
No increase in the maximum number of repeats may be authorised.								
3414Q NP	nicotine 21 mg/24 hours patch, 28	1	2	..	55.43	36.10	Nicotinell Step 1	NC
5572G NP	nicotine 14 mg/24 hours patch, 28	1	2	..	55.43	36.10	Nicotinell Step 2	NC
5573H NP	nicotine 7 mg/24 hours patch, 28	1	2	..	55.43	36.10	Nicotinell Step 3	NC
NICOTINE								
<u>Authority required (STREAMLINED)</u>								
4344								
Nicotine dependence								
The Population criteria is:								
Patient must be an Aboriginal or a Torres Strait Islander person,								
AND the Clinical criteria is:								
The treatment must be the sole PBS-subsidised therapy for this condition.								
<u>Note</u>								
Only 2 courses of PBS-subsidised nicotine replacement therapy may be prescribed per 12-month period.								
Benefit is improved if used in conjunction with a comprehensive support and counselling program.								
<u>Note</u>								
No increase in the maximum quantity or number of units may be authorised.								
<u>Note</u>								
No increase in the maximum number of repeats may be authorised.								
5571F NP	nicotine 21 mg/24 hours patch, 28	1	2	..	55.43	36.10	Nicotinell Step 1	NC
OLMESARTAN + AMLODIPINE + HYDROCHLOROTHIAZIDE								
<u>Restricted benefit</u>								
Hypertension								
The Clinical criteria is:								
The treatment must not be for the initiation of anti-hypertensive therapy,								
AND the Clinical criteria is:								
The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.								
10005N NP	olmesartan medoxomil 20 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	21.06	22.19	Sevikar HCT 20/5/12.5	MK
2880N NP	olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	31.36	32.49	Sevikar HCT 40/5/12.5	MK
2864R NP	olmesartan medoxomil 40 mg + amlodipine 5 mg + hydrochlorothiazide	1	5	..	33.59	34.72	Sevikar HCT 40/5/25	MK

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
2836G NP	25 mg tablet, 30 olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	33.63	34.76	Sevikar HCT 40/10/12.5	MK
2953K NP	olmesartan medoxomil 40 mg + amlodipine 10 mg + hydrochlorothiazide 25 mg tablet, 30	1	5	..	35.86	36.10	Sevikar HCT 40/10/25	MK

PILOCARPINE

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5536J OP	pilocarpine hydrochloride 1% eye drops, 15 mL	£1	5	..	12.74	13.87	Isopto Carpine	AQ
5537K OP	pilocarpine hydrochloride 2% eye drops, 15 mL	£1	5	..	13.99	15.12	Isopto Carpine	AQ
5538L OP	pilocarpine hydrochloride 4% eye drops, 15 mL	£1	5	..	16.84	17.97	Isopto Carpine	AQ

RIFAXIMIN

Authority required

Prevention of hepatic encephalopathy

The Treatment criteria is:

Must be treated by a gastroenterologist or hepatologist or in consultation with a gastroenterologist or hepatologist,

AND the Clinical criteria is:

The treatment must be in combination with lactulose, if lactulose is tolerated,

AND the Clinical criteria is:

Patient must have had prior episodes of hepatic encephalopathy.

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.

10001J	rifaximin 550 mg tablet, 56	1	5	..	494.97	36.10	Xifaxan	NE
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SAXAGLIPTIN

Authority required (STREAMLINED)

4350

Diabetes mellitus type 2

The Clinical criteria is:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND the Clinical criteria is:

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR

Patient must not have tolerated a combination of metformin and a sulfonylurea,

AND the Clinical criteria is:

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note

This drug is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

8983T NP	saxagliptin 5 mg tablet, 28	1	5	..	90.81	36.10	Onglyza	BQ
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SITAGLIPTIN

Authority required (STREAMLINED)

4350

Diabetes mellitus type 2

The Clinical criteria is:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND the Clinical criteria is:

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR

Patient must not have tolerated a combination of metformin and a sulfonylurea,

AND the Clinical criteria is:

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note

This drug is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

9180E NP	sitagliptin 25 mg tablet, 28	1	5	..	90.81	36.10	Januvia	MK
9181F NP	sitagliptin 50 mg tablet, 28	1	5	..	90.81	36.10	Januvia	MK
9182G NP	sitagliptin 100 mg tablet, 28	1	5	..	90.81	36.10	Januvia	MK

SITAGLIPTIN + METFORMIN

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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Authority required (STREAMLINED)

4325

Diabetes mellitus type 2

The Clinical criteria is:

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR

Patient must not have tolerated a combination of metformin and a sulfonylurea,

AND the Clinical criteria is:

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with metformin; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with metformin.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Authority required (STREAMLINED)

4309

Diabetes mellitus type 2

Treatment Phase: Continuing

The Clinical criteria is:

Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin.

Note

This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

9449H NP	sitagliptin 50 mg + metformin hydrochloride 500 mg tablet, 56	1	5	..	93.20	36.10	Janumet	MK
9450J NP	sitagliptin 50 mg + metformin hydrochloride 850 mg tablet, 56	1	5	..	94.80	36.10	Janumet	MK
9451K NP	sitagliptin 50 mg + metformin hydrochloride 1 g tablet, 56	1	5	..	95.44	36.10	Janumet	MK

SUNITINIB

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Initial treatment

The Clinical criteria is:

Patient must be symptomatic (despite somatostatin analogues); OR

Patient must have disease progression,

AND the Clinical criteria is:

The treatment must be as monotherapy.

Disease progression must be documented in the patient's medical records.

Note

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
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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.

10004M	sunitinib 12.5 mg capsule, 28	1	2	..	1834.41	36.10	Sutent	PF
2959R	sunitinib 25 mg capsule, 28	1	2	..	3521.97	36.10	Sutent	PF
2837H	sunitinib 50 mg capsule, 28	1	2	..	6897.65	36.10	Sutent	PF

SUNITINIB

Authority required

Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)

Treatment Phase: Continuing treatment

The Clinical criteria is:

Patient must have previously been issued with an authority prescription for sunitinib,

AND the Clinical criteria is:

Patient must not have progressive disease,

AND the Clinical criteria is:

The treatment must be as monotherapy.

Note

Patients who have progressive disease with sunitinib are no longer eligible for PBS-subsidised sunitinib.

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.

10009T	sunitinib 12.5 mg capsule, 28	1	5	..	1834.41	36.10	Sutent	PF
2842N	sunitinib 25 mg capsule, 28	1	5	..	3521.97	36.10	Sutent	PF
10010W	sunitinib 50 mg capsule, 28	1	5	..	6897.65	36.10	Sutent	PF

T AFLUPROST

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

2748P OP	tafluprost 0.0015% eye drops, 30 x 0.3 mL unit doses	#1	5	..	34.03	35.16	Saflutan	MK
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TERBUTALINE

2817G NP	terbutaline sulfate 500 microgram/actuation inhalation: powder for, 100 actuations	2	5	..	*18.07	19.20	Bricanyl Turbuhaler	AP
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TERIFLUNOMIDE

Authority required

Multiple sclerosis

Treatment Phase: Initial treatment

The Clinical criteria is:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,

AND the Clinical criteria is:

The treatment must be as monotherapy,

AND the Clinical criteria is:

Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years; OR

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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Patient must have been receiving treatment with this drug prior to 1 December 2013,

AND the Clinical criteria is:

Patient must be ambulatory (without assistance or support).

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

Authority required

Multiple sclerosis

Treatment Phase: Continuing treatment

The Clinical criteria is:

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR

The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient,

AND the Clinical criteria is:

The treatment must be as monotherapy,

AND the Clinical criteria is:

Patient must have previously been issued with an authority prescription for this drug,

AND the Clinical criteria is:

Patient must not show continuing progression of disability while on treatment with this drug.

Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application.

Caution

Teriflunomide is a category X drug and must not be given to pregnant women or women of childbearing potential who are not currently using reliable contraception.

Pregnancy should be avoided for two years after cessation of therapy, unless special wash-out procedures are carried out.

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.

2898M	teriflunomide 14 mg tablet, 28	1	5	..	1847.13	36.10	Aubagio	GZ
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TIMOLOL

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5546X <i>OP</i>	timolol 0.1% eye gel, 5 g	#1	5	..	13.08	14.21	Nyogel	AS
5547Y <i>OP</i>	timolol 0.25% (2.5 mg/mL) eye drops, 5 mL	#1	5	..	11.75	12.88	Tenopt	QA
5549C <i>OP</i>	timolol 0.25% (2.5 mg/mL) eye drops, 2.5 mL	#1	5	..	11.75	12.88	Timoptol XE	MK
5548B <i>OP</i>	timolol 0.5% (5 mg/mL) eye drops, 5 mL	#1	5	..	12.52	13.65	^a Tenopt	QA
				^b 3.03	15.55	13.65	^a Timoptol	FR
5550D <i>OP</i>	timolol 0.5% (5 mg/mL) eye drops, 2.5 mL	#1	5	..	12.52	13.65	Timoptol XE	MK

TIMOLOL + TRAVOPROST

Restricted benefit

Elevated intra-ocular pressure

The Clinical criteria is:

The condition must have been inadequately controlled with monotherapy,

AND the Clinical criteria is:

Patient must have open-angle glaucoma; OR

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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Patient must have ocular hypertension.

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5555J OP	timolol 0.5% + travoprost 0.004% eye drops, 2.5 mL	1	5	..	46.81	36.10	Duotrav	AQ
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TRAVOPROST

Note

Shared Care Model:

For prescribing by optometrists where care of a patient is shared between an optometrist and ophthalmologist in a formalised arrangement with an agreed management plan. Further information can be found in the Guidelines for Shared Care of Glaucoma Patients.

5554H OP	travoprost 0.004% (40 microgram/mL) eye drops, 2.5 mL	1	5	..	42.35	36.10	Travatan	AQ
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VILDAGLIPTIN

Authority required (STREAMLINED)

4350

Diabetes mellitus type 2

The Clinical criteria is:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

AND the Clinical criteria is:

Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR

Patient must not have tolerated a combination of metformin and a sulfonylurea,

AND the Clinical criteria is:

Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR

Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea.

The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.

The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.

Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:

- (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or
- (b) Had red cell transfusion within the previous 3 months.

The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.

Note

This drug is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.

3415R NP	vildagliptin 50 mg tablet, 60	1	5	..	96.82	36.10	Galvus	NV
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VILDAGLIPTIN + METFORMIN

Authority required (STREAMLINED)

4325

Diabetes mellitus type 2

GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer		
	The Clinical criteria is:								
	Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR								
	Patient must not have tolerated a combination of metformin and a sulfonylurea,								
	AND the Clinical criteria is:								
	Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with metformin; OR								
	Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with metformin.								
	The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated.								
	The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated.								
	Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances:								
	(a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or								
	(b) Had red cell transfusion within the previous 3 months.								
	The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records.								
	<u>Authority required (STREAMLINED)</u>								
	4308								
	Diabetes mellitus type 2								
	Treatment Phase: Continuing								
	The Clinical criteria is:								
	Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin.								
	<u>Note</u>								
	This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), as initial therapy or in combination with a thiazolidinedione (glitazone), a glucagon-like peptide-1 or an SGLT2 inhibitor.								
5474D NP	vildagliptin 50 mg + metformin hydrochloride 500 mg tablet, 60	1	5	..	96.30	36.10	Galvumet 50/500	NV	
5475E NP	vildagliptin 50 mg + metformin hydrochloride 850 mg tablet, 60	1	5	..	98.01	36.10	Galvumet 50/850	NV	
5476F NP	vildagliptin 50 mg + metformin hydrochloride 1 g tablet, 60	1	5	..	98.70	36.10	Galvumet 50/1000	NV	
	WHEY PROTEIN FORMULA SUPPLEMENTED WITH AMINO ACIDS, LONG CHAIN POLYUNSATURATED FATTY ACIDS, VITAMINS AND MINERALS, LOW IN PROTEIN, PHOSPHATE, POTASSIUM AND LACTOSE								
	<u>Authority required</u>								
	Chronic renal failure								
	The Population criteria is:								
	Patient must be an infant or a young child,								
	AND the Clinical criteria is:								
	Patient must require treatment with a low protein, low phosphorus and low potassium diet; OR								
	Patient must require treatment with a low protein and a low phosphorus diet.								
2870C NP	whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, low in protein, phosphate, potassium and lactose oral liquid: powder for, 6 x 400 g cans	4	5	..	*1584.47	36.10	Renastart	VF	

HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
DARUNAVIR						
<u>Authority required (STREAMLINED)</u>						
4313						
Human immunodeficiency virus (HIV) infection						
The Clinical criteria is:						
The treatment must be in addition to optimised background therapy,						
AND the Clinical criteria is:						
The treatment must be in combination with other antiretroviral agents,						
AND the Clinical criteria is:						
The treatment must be co-administered with 100 mg ritonavir,						
AND the Clinical criteria is:						
Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen,						
AND the Clinical criteria is:						
Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing.						
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.						
2980W	darunavir 800 mg tablet, 30	2	5	..	*1398.28	Prezista JC

HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
DARUNAVIR						
<u>Authority required</u>						
Human immunodeficiency virus (HIV) infection						
The Clinical criteria is:						
The treatment must be in addition to optimised background therapy,						
AND the Clinical criteria is:						
The treatment must be in combination with other antiretroviral agents,						
AND the Clinical criteria is:						
The treatment must be co-administered with 100 mg ritonavir,						
AND the Clinical criteria is:						
Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen,						
AND the Clinical criteria is:						
Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing.						
Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.						
10000H	darunavir 800 mg tablet, 30	2	5	..	*1444.91	Prezista JC