



Australian Government

**Department of Health
and Aged Care**



Schedule of Pharmaceutical Benefits

Summary of Changes

Effective 1 September 2024



Fees, Patient Contributions and Safety Net Thresholds

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

Dispensing Fees:	Ready-prepared	\$8.67
	Dangerous drug fee	\$5.37
	Extemporaneously-prepared	\$10.71
	Allowable additional patient charge*	\$3.45
Additional Fees (for safety net prices):	Ready-prepared	\$1.45
	Extemporaneously-prepared	\$1.87
Patient Co-payments:	General	\$31.60
	Concessional	\$7.70
Safety Net Thresholds:	General	\$1647.90
	Concessional	\$277.20
Safety Net Card Issue Fee:		\$12.04

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

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 September 2024. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

General Pharmaceutical Benefits

Additions

Addition – Item

- 14539F **ACLIDINIUM**, acclidinium 322 microgram/actuation inhalation: powder for, 60 actuations (*Bretaris Genuair*)
- 14410K **ACLIDINIUM + FORMOTEROL**, acclidinium 340 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations (*Brimica Genuair*)
- 14486K **AMANTADINE**, amantadine hydrochloride 100 mg capsule, 100 (*AMANTAMED, Symmetrel 100*)
- 14568R **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 100 mL (*CLAVULIN-125F (GlaxoSmithKline, Canada)*)
- 14569T **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 100 mL (*CLAVULIN-125F (GlaxoSmithKline, Canada)*)
- 14407G **APOMORPHINE**, apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules (*Movapo*)
- 14375N **APOMORPHINE**, apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials (*Apomine Solution for Infusion*)
- 14309D **APOMORPHINE**, apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges (*Apomine Intermittent*)
- 14485J **APOMORPHINE**, apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices (*Movapo Pen*)
- 14377Q **APOMORPHINE**, apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes (*Movapo PFS*)
- 14566P **ATEZOLIZUMAB**, atezolizumab 1.875 g/15 mL injection, 15 mL vial (*Tecentriq SC*)
- 14570W **AZITHROMYCIN**, azithromycin 200 mg/5 mL powder for oral liquid, 15 mL (*Azithromycin (Zydus, USA)*)
- 14378R **BECLOMETASONE**, beclometasone dipropionate 50 microgram/actuation breath activated inhalation, 200 actuations (*Qvar 50 Autohaler*)
- 14540G **BECLOMETASONE**, beclometasone dipropionate 50 microgram/actuation inhalation, 200 actuations (*Qvar 50*)
- 14514X **BECLOMETASONE**, beclometasone dipropionate 100 microgram/actuation breath activated inhalation, 200 actuations (*Qvar 100 Autohaler*)
- 14541H **BECLOMETASONE**, beclometasone dipropionate 100 microgram/actuation inhalation, 200 actuations (*Qvar 100*)
- 14376P **BECLOMETASONE + FORMOTEROL**, beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations (*Fostair*)
- 14538E **BECLOMETASONE + FORMOTEROL**, beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations (*Fostair 200/6*)
- 14310E **BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM**, beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations (*Trimbrow*)
- 14425F **BETAXOLOL**, betaxolol 0.5% eye drops, 5 mL (*BetoQuin, Betoptic*)
- 14422C **BIMATOPROST**, bimatoprost 0.03% eye drops, 30 x 0.4 mL ampoules (*Lumigan PF*)
- 14315K **BIMATOPROST**, bimatoprost 0.03% eye drops, 3 mL (*BIMATOPROST-WGR, Bimatoprost Sandoz, Bimprozt, Bimtop, Lumigan*)
- 14317M **BIMATOPROST + TIMOLOL**, bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL (*Ganfort 0.3/5*)

14351H	BIMATOPROST + TIMOLOL , bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL ampoules (<i>GANfort PF 0.3/5</i>)
14447J	BISACODYL , bisacodyl 10 mg suppository, 10 (<i>Dulcolax, Petrus Bisacodyl Suppositories</i>)
14305X	BISACODYL , bisacodyl 10 mg suppository, 12 (<i>Petrus Bisacodyl Suppositories</i>)
14446H	BISACODYL , bisacodyl 5 mg enteric tablet, 200 (<i>Lax-Tab</i>)
14496Y	BRIMONIDINE , brimonidine tartrate 0.15% eye drops, 5 mL (<i>Alphagan P 1.5</i>)
14497B	BRIMONIDINE , brimonidine tartrate 0.2% eye drops, 5 mL (<i>Alphagan, Enidin</i>)
14491Q	BRIMONIDINE + TIMOLOL , brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL (<i>Combigan</i>)
14321R	BRINZOLAMIDE , brinzolamide 1% eye drops, 5 mL (<i>Azopt, BrinzoQuin</i>)
14423D	BRINZOLAMIDE + BRIMONIDINE , brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL (<i>Simbrinza 1%/0.2%</i>)
14495X	BRINZOLAMIDE + TIMOLOL , brinzolamide 1% + timolol 0.5% eye drops, 5 mL (<i>Azarga</i>)
14571X	BUDESONIDE , budesonide 3 mg enteric capsule, 50 (<i>Budenofalk</i>)
14438X	BUDESONIDE , budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules (<i>Pulmicort Respules</i>)
14469M	BUDESONIDE , budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules (<i>Pulmicort Respules</i>)
14331G	BUDESONIDE , budesonide 100 microgram/actuation powder for inhalation, 200 actuations (<i>Pulmicort Turbuhaler</i>)
14503H	BUDESONIDE , budesonide 200 microgram/actuation powder for inhalation, 200 actuations (<i>Pulmicort Turbuhaler</i>)
14470N	BUDESONIDE , budesonide 400 microgram/actuation powder for inhalation, 200 actuations (<i>Pulmicort Turbuhaler</i>)
14467K	BUDESONIDE + FORMOTEROL , budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations (<i>Rilast RAPIHALER 100/3, Symbicort Rapihaler 100/3</i>)
14535B	BUDESONIDE + FORMOTEROL , budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations (<i>Rilast RAPIHALER 100/3, Symbicort Rapihaler 100/3</i>)
14436T	BUDESONIDE + FORMOTEROL , budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations (<i>Rilast RAPIHALER 200/6, Symbicort Rapihaler 200/6</i>)
14468L	BUDESONIDE + FORMOTEROL , budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations (<i>Rilast RAPIHALER 200/6, Symbicort Rapihaler 200/6</i>)
14437W	BUDESONIDE + FORMOTEROL , budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (<i>Symbicort Turbuhaler 100/6</i>)
14440B	BUDESONIDE + FORMOTEROL , budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (<i>Symbicort Turbuhaler 100/6</i>)
14365C	BUDESONIDE + FORMOTEROL , budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (<i>BiResp Spiromax, DuoResp Spiromax, Rilast TURBUHALER 200/6, Symbicort Turbuhaler 200/6</i>)
14434Q	BUDESONIDE + FORMOTEROL , budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (<i>BiResp Spiromax, DuoResp Spiromax</i>)
14439Y	BUDESONIDE + FORMOTEROL , budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations (<i>Rilast TURBUHALER 200/6, Symbicort Turbuhaler 200/6</i>)
14398T	BUDESONIDE + FORMOTEROL , budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations (<i>Bufomix Easyhaler 400/12, DuoResp Spiromax, Rilast TURBUHALER 400/12, Symbicort TURBUHALER 400/12</i>)
14435R	BUDESONIDE + FORMOTEROL , budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations (<i>BiResp Spiromax, DuoResp Spiromax</i>)
14536C	BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL , budesonide 160 microgram/actuation + glycopyrronium 7.2 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations (<i>Breztri Aerosphere</i>)
14516B	CABERGOLINE , cabergoline 1 mg tablet, 30 (<i>Cabaser</i>)
14543K	CABERGOLINE , cabergoline 2 mg tablet, 30 (<i>Cabaser</i>)
14509P	CARBAMAZEPINE , carbamazepine 100 mg tablet, 100 (<i>Carbamazepine Sandoz, Tegretol 100</i>)
14338P	CARBAMAZEPINE , carbamazepine 200 mg tablet, 100 (<i>Carbamazepine Sandoz, Tegretol 200</i>)
14420Y	CARBOMER-980 , carbomer-980 0.2% eye drops, 30 x 600 mg ampoules (<i>Viscotears Gel PF</i>)
14385D	CARBOMER-980 , carbomer-980 0.2% eye gel, 10 g (<i>Optifresh eye gel, PAA, Viscotears</i>)
14522H	CARMELLOSE SODIUM , carmellose sodium 0.5% eye drops, 30 x 0.4 mL ampoules (<i>Cellufresh</i>)
14319P	CARMELLOSE SODIUM , carmellose sodium 0.5% eye drops, 10 mL (<i>Evolve Carmellose</i>)
14452P	CARMELLOSE SODIUM , carmellose sodium 1% eye drops, 30 x 0.4 mL ampoules (<i>Celluvisc</i>)

14312G **CICLESONIDE**, ciclesonide 80 microgram/actuation inhalation, 120 actuations (*Alvesco 80*)

14348E **CICLESONIDE**, ciclesonide 160 microgram/actuation inhalation, 120 actuations (*Alvesco 160*)

14313H **CITALOPRAM**, citalopram 10 mg tablet, 28 (*Celapram, Talam*)

14490P **CITALOPRAM**, citalopram 20 mg tablet, 28 (*APO-Citalopram, APX-Citalopram, Celapram, Cipramil, Citalopram Sandoz, NOUMED CITALOPRAM, Talam*)

14518D **CITALOPRAM**, citalopram 40 mg tablet, 28 (*APO-Citalopram, Celapram, Citalopram Sandoz, NOUMED CITALOPRAM, Talam*)

14534Y **CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL**, sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL (*Micolette*)

14477Y **COLESTYRAMINE**, colestyramine 4 g powder for oral liquid, 50 sachets (*Questran Lite*)

14383B **DESVENLAFAXINE**, desvenlafaxine 50 mg modified release tablet, 28 (*BTC Desvenlafaxine, DESVEN, DESVENLAFAXINE-WGR XR, Desfax, Desvenlafaxine Sandoz*)

14418W **DESVENLAFAXINE**, desvenlafaxine 50 mg modified release tablet, 28 (*APO-Desvenlafaxine MR, Desvenlafaxine GH XR*)

14451N **DESVENLAFAXINE**, desvenlafaxine 50 mg modified release tablet, 28 (*Pristiq*)

14384C **DESVENLAFAXINE**, desvenlafaxine 100 mg modified release tablet, 28 (*APO-Desvenlafaxine MR, Desvenlafaxine GH XR*)

14489N **DESVENLAFAXINE**, desvenlafaxine 100 mg modified release tablet, 28 (*BTC Desvenlafaxine, DESVEN, DESVENLAFAXINE-WGR XR, Desfax, Desvenlafaxine Sandoz*)

14545M **DESVENLAFAXINE**, desvenlafaxine 100 mg modified release tablet, 28 (*Pristiq*)

14521G **DEXTRAN-70 + HYPROMELLOSE**, dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL (*Poly-Tears, Tears Naturale*)

14564M **DILTIAZEM**, diltiazem hydrochloride 180 mg modified release capsule, 30 (*Cardizem CD, Diltiazem Sandoz CD, Vasocardol CD*)

14508N **DILTIAZEM**, diltiazem hydrochloride 240 mg modified release capsule, 30 (*Cardizem CD, Diltiazem Sandoz CD, Vasocardol CD*)

14565N **DILTIAZEM**, diltiazem hydrochloride 360 mg modified release capsule, 30 (*Cardizem CD, Diltiazem Sandoz CD, Vasocardol CD*)

14479C **DILTIAZEM**, diltiazem hydrochloride 60 mg tablet, 90 (*Cardizem, Vasocardol*)

14524K **DORZOLAMIDE**, dorzolamide 2% eye drops, 5 mL (*Trusamide, Trusopt*)

14386E **DORZOLAMIDE + TIMOLOL**, dorzolamide 2% + timolol 0.5% eye drops, 5 mL (*Cosdor, Cosopt, Vizo-PF Dorzolatim*)

14484H **DOXYCYCLINE**, doxycycline 50 mg modified release capsule, 25 (*Doryx, Mayne Pharma Doxycycline*)

14443E **DOXYCYCLINE**, doxycycline 100 mg modified release capsule, 7 (*Doryx, Mayne Pharma Doxycycline*)

14307B **DOXYCYCLINE**, doxycycline 50 mg tablet, 25 (*APX-Doxycycline, DOXYCYCLINE-WGR, Doxsig, Doxylin 50*)

14513W **DOXYCYCLINE**, doxycycline 50 mg tablet, 25 (*Doxycycline Sandoz*)

14480D **DOXYCYCLINE**, doxycycline 100 mg tablet, 7 (*APX-Doxycycline, DOXYCYCLINE-WGR, Doxsig, Doxylin 100*)

14511R **DOXYCYCLINE**, doxycycline 100 mg tablet, 7 (*Doxycycline Sandoz*)

14542J **ENTACAPONE**, entacapone 200 mg tablet, 100 (*Comtan*)

14337N **EPROSARTAN + HYDROCHLOROTHIAZIDE**, eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28 (*Teveten Plus 600/12.5*)

14409J **ERYTHROMYCIN**, erythromycin 250 mg enteric capsule, 25 (*Mayne Pharma Erythromycin*)

14546N **ESCITALOPRAM**, escitalopram 20 mg/mL oral liquid, 15 mL (*Lexapro*)

14349F **ESCITALOPRAM**, escitalopram 10 mg tablet, 28 (*APO-Escitalopram, APX-Escitalopram, Blooms Escitalopram, Cilopam-S, Escitalopram GH, Escitalopram Sandoz, Esipram, Lexam 10, Lexapro, LoxaLate, NOUMED ESCITALOPRAM*)

14519E **ESCITALOPRAM**, escitalopram 10 mg tablet, 28 (*APO-Escitalopram, APX-Escitalopram, Blooms Escitalopram, Escitalopram GH, Escitalopram Sandoz, Esipram, Lexam 10, Lexapro, LoxaLate, NOUMED ESCITALOPRAM*)

14415Q **ESCITALOPRAM**, escitalopram 20 mg tablet, 28 (*APO-Escitalopram, APX-Escitalopram, Blooms Escitalopram, Cilopam-S, Escitalopram GH, Escitalopram Sandoz, Esipram, Lexam 20, Lexapro, LoxaLate, NOUMED ESCITALOPRAM*)

14416R **ESCITALOPRAM**, escitalopram 20 mg tablet, 28 (*APO-Escitalopram, APX-Escitalopram, Blooms Escitalopram, Escitalopram GH, Escitalopram Sandoz, Esipram, Lexam 20, Lexapro, NOUMED ESCITALOPRAM*)

14303T **ESOMEPRAZOLE**, esomeprazole 20 mg enteric capsule, 30 (*Noxicid Caps*)

14510Q **ESOMEPRAZOLE**, esomeprazole 20 mg enteric capsule, 30 (*Noxicid Caps*)

14537D **ESOMEPRAZOLE**, esomeprazole 20 mg enteric capsule, 30 (*Noxicid Caps*)

14405E	ESOMEPRAZOLE , esomeprazole 40 mg enteric capsule, 30 (<i>Noxicid Caps</i>)
14445G	ESOMEPRAZOLE , esomeprazole 40 mg enteric capsule, 30 (<i>Noxicid Caps</i>)
14308C	ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30 (<i>APO-Esomeprazole, ESOMEPRAZOLE-WGR, Esomeprazole GH, Esomeprazole GxP, Esomeprazole Mylan, Esomeprazole RBX, Esomeprazole Viartis, Esopreze, NOUMED ESOMEPRAZOLE, Nexazole, Nexium, Nexole</i>)
14444F	ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30 (<i>APO-Esomeprazole, ESOMEPRAZOLE-WGR, Esomeprazole GH, Esomeprazole GxP, Esomeprazole Mylan, Esomeprazole RBX, Esomeprazole Viartis, Esopreze, NOUMED ESOMEPRAZOLE, Nexazole, Nexium, Nexole</i>)
14481E	ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30 (<i>APO-Esomeprazole, ESOMEPRAZOLE-WGR, Esomeprazole GH, Esomeprazole GxP, Esomeprazole Mylan, Esomeprazole RBX, Esomeprazole Viartis, Esopreze, NOUMED ESOMEPRAZOLE, Nexazole, Nexium, Nexole</i>)
14373L	ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30 (<i>APO-Esomeprazole, ESOMEPRAZOLE-WGR, Esomeprazole GH, Esomeprazole GxP, Esomeprazole Mylan, Esomeprazole RBX, Esomeprazole Viartis, Esopreze, NOUMED ESOMEPRAZOLE, Nexazole, Nexium, Nexole</i>)
14512T	ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30 (<i>APO-Esomeprazole, ESOMEPRAZOLE-WGR, Esomeprazole GH, Esomeprazole GxP, Esomeprazole Mylan, Esomeprazole RBX, Esomeprazole Viartis, Esopreze, NOUMED ESOMEPRAZOLE, Nexazole, Nexium, Nexole</i>)
14336M	ESTRADIOL + NORETHISTERONE ACETATE , estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8 (<i>Estalis continuous 50/250</i>)
14548Q	FLUOXETINE , fluoxetine 20 mg capsule, 28 (<i>APO-Fluoxetine, Blooms the Chemist Fluoxetine, FLUOTEX, Fluoxetine APOTEX, Fluoxetine Sandoz, Fluoxetine generichealth, NOUMED FLUOXETINE, Prozac 20, Zactin</i>)
14515Y	FLUTICASONE FUROATE , fluticasone furoate 100 microgram/actuation powder for inhalation, 30 actuations (<i>Arnuity Ellipta</i>)
14380W	FLUTICASONE FUROATE , fluticasone furoate 200 microgram/actuation powder for inhalation, 30 actuations (<i>Arnuity Ellipta</i>)
14346C	FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL , fluticasone furoate 100 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations (<i>Trelegy Ellipta 100/62.5/25</i>)
14382Y	FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL , fluticasone furoate 200 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations (<i>Trelegy Ellipta 200/62.5/25</i>)
14379T	FLUTICASONE FUROATE + VILANTEROL , fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations (<i>Breo Ellipta 100/25</i>)
14345B	FLUTICASONE FUROATE + VILANTEROL , fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations (<i>Breo Ellipta 200/25</i>)
14487L	FLUTICASONE PROPIONATE , fluticasone propionate 50 microgram/actuation inhalation, 120 actuations (<i>Axotide Junior, Flixotide Junior</i>)
14347D	FLUTICASONE PROPIONATE , fluticasone propionate 125 microgram/actuation inhalation, 120 actuations (<i>Axotide, Flixotide, Fluticasone Cipla Inhaler</i>)
14412M	FLUTICASONE PROPIONATE , fluticasone propionate 100 microgram/actuation powder for inhalation, 60 actuations (<i>Axotide Junior Accuhaler, Flixotide Junior Accuhaler</i>)
14381X	FLUTICASONE PROPIONATE , fluticasone propionate 250 microgram/actuation powder for inhalation, 60 actuations (<i>Axotide Accuhaler, Flixotide Accuhaler</i>)
14411L	FLUTICASONE PROPIONATE + FORMOTEROL , fluticasone propionate 50 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations (<i>flutiform 50/5</i>)
14343X	FLUTICASONE PROPIONATE + FORMOTEROL , fluticasone propionate 125 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations (<i>flutiform 125/5</i>)
14344Y	FLUTICASONE PROPIONATE + FORMOTEROL , fluticasone propionate 250 microgram/actuation + formoterol fumarate dihydrate 10 microgram/actuation inhalation, 120 actuations (<i>flutiform 250/10</i>)
14414P	FLUTICASONE PROPIONATE + SALMETEROL , fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations (<i>PAVTIDE MDI 50/25, Seretide MDI 50/25</i>)
14544L	FLUTICASONE PROPIONATE + SALMETEROL , fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations (<i>Evocair MDI, Fluticasone + Salmeterol Cipla 125/25, Pavtide, SalplusF Inhaler 125/25, Seretide MDI 125/25</i>)
14311F	FLUTICASONE PROPIONATE + SALMETEROL , fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations (<i>Evocair MDI, Fluticasone + Salmeterol Cipla 250/25, Pavtide, SalplusF Inhaler 250/25, Seretide MDI 250/25</i>)
14413N	FLUTICASONE PROPIONATE + SALMETEROL , fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations (<i>PAVTIDE ACCUHALER 100/50, Seretide Accuhaler 100/50</i>)

14449L **FLUTICASONE PROPIONATE + SALMETEROL**, fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations (*Fluticasone Salmeterol Ciphaler 250/50, PAVTIDE ACCUHALER 250/50, Salfumix Easyhaler 250/50, SalplusF DPI 250/50, Seretide Accuhaler 250/50*)

14450M **FLUTICASONE PROPIONATE + SALMETEROL**, fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations (*Fluticasone Salmeterol Ciphaler 500/50, PAVTIDE ACCUHALER 500/50, Salfumix Easyhaler 500/50, SalplusF DPI 500/50, Seretide Accuhaler 500/50*)

14488M **FLUVOXAMINE**, fluvoxamine maleate 50 mg tablet, 30 (*APO-Fluvoxamine, FLUVOXAMINE-WGR, Faverin 50, Luvox, Movox 50*)

14314J **FLUVOXAMINE**, fluvoxamine maleate 100 mg tablet, 30 (*APO-Fluvoxamine, FLUVOXAMINE-WGR, Faverin 100, Luvox, Movox 100*)

14419X **FORMOTEROL**, formoterol fumarate dihydrate 12 microgram powder for inhalation, 60 capsules (*Foradile*)

14547P **FORMOTEROL**, formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations (*Oxis Turbuhaler*)

14517C **FORMOTEROL**, formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations (*Oxis Turbuhaler*)

14371J **GLYCERYL TRINITRATE**, glyceryl trinitrate 5 mg/24 hours patch, 30 (*Minitran 5*)

14478B **GLYCERYL TRINITRATE**, glyceryl trinitrate 10 mg/24 hours patch, 30 (*Minitran 10*)

14335L **GLYCERYL TRINITRATE**, glyceryl trinitrate 15 mg/24 hours patch, 30 (*Minitran 15*)

14417T **GLYCOPYRRONIUM**, glycopyrronium 50 microgram powder for inhalation, 30 capsules (*seebri breezhaler*)

14354L **HYALURONATE SODIUM**, hyaluronate sodium 0.1% eye drops, 10 mL (*Hylo-Fresh*)

14494W **HYALURONATE SODIUM**, hyaluronate sodium 0.2% eye drops, 10 mL (*Hylo-Forte*)

14476X **HYDROCORTISONE**, hydrocortisone 20 mg tablet, 60 (*Hydrocortisone Viatrix 20, Hysone 20*)

14492R **HYPROMELLOSE**, hypromellose 0.3% w/v eye drops, 10 mL (*Evolve Hypromellose*)

14318N **HYPROMELLOSE**, hypromellose 0.3% w/w eye drops, 10 mL (*Gentel, In a Wink Moisturising, Revive Tears*)

14320Q **HYPROMELLOSE**, hypromellose 0.5% eye drops, 15 mL (*Methopt*)

14334K **INDACATEROL**, indacaterol 150 microgram powder for inhalation, 30 capsules (*Onbrez*)

14368F **INDACATEROL**, indacaterol 300 microgram powder for inhalation, 30 capsules (*Onbrez*)

14504J **INDACATEROL + GLYCOPYRRONIUM**, indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules (*ultibro breezhaler 110/50*)

14399W **INDACATEROL + GLYCOPYRRONIUM + MOMETASONE**, indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 136 microgram powder for inhalation, 30 capsules (*Enerzair Breezhaler*)

14471P **INDACATEROL + GLYCOPYRRONIUM + MOMETASONE**, indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 68 microgram powder for inhalation, 30 capsules (*Enerzair Breezhaler*)

14332H **INDACATEROL + MOMETASONE**, indacaterol 125 microgram + mometasone furoate 62.5 microgram powder for inhalation, 30 capsules (*Ateectura Breezhaler*)

14333J **INDACATEROL + MOMETASONE**, indacaterol 125 microgram + mometasone furoate 127.5 microgram powder for inhalation, 30 capsules (*Ateectura Breezhaler*)

14441C **INDACATEROL + MOMETASONE**, indacaterol 125 microgram + mometasone furoate 260 microgram powder for inhalation, 30 capsules (*Ateectura Breezhaler*)

14448K **LANSOPRAZOLE**, lansoprazole 15 mg enteric capsule, 30 (*Zopral*)

14302R **LANSOPRAZOLE**, lansoprazole 30 mg enteric capsule, 28 (*APO-Lansoprazole, Lanzopran, NOUMED LANSOPRAZOLE, Zopral*)

14304W **LANSOPRAZOLE**, lansoprazole 30 mg enteric capsule, 28 (*APO-Lansoprazole, Lanzopran, NOUMED LANSOPRAZOLE, Zopral*)

14340R **LANSOPRAZOLE**, lansoprazole 30 mg enteric capsule, 28 (*APO-Lansoprazole, Lanzopran, NOUMED LANSOPRAZOLE, Zopral*)

14374M **LANSOPRAZOLE**, lansoprazole 15 mg orally disintegrating tablet, 28 (*APO-Lansoprazole ODT, Lansoprazole ODT GH, Zopral ODT, Zoton FasTabs*)

14339Q **LANSOPRAZOLE**, lansoprazole 30 mg orally disintegrating tablet, 28 (*APO-Lansoprazole ODT, Lansoprazole ODT GH, Zopral ODT, Zoton FasTabs*)

14342W **LANSOPRAZOLE**, lansoprazole 30 mg orally disintegrating tablet, 28 (*APO-Lansoprazole ODT, Lansoprazole ODT GH, Zopral ODT, Zoton FasTabs*)

14406F **LANSOPRAZOLE**, lansoprazole 30 mg orally disintegrating tablet, 28 (*APO-Lansoprazole ODT, Lansoprazole ODT GH, Zopral ODT, Zoton FasTabs*)

14453Q **LATANOPROST**, latanoprost 0.005% eye drops, 2.5 mL (*APO-Latanoprost, LATANOPROST-WGR, Latanoprost Sandoz, Xalaprost, Xalatan*)

14350G	LATANOPROST + TIMOLOL , latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL (<i>APO-Latanoprost/Timolol 0.05/5, Xalacom, Xalamol 50/5</i>)
14388G	LEVODOPA + BENSERAZIDE , levodopa 50 mg + benserazide 12.5 mg capsule, 100 (<i>Madopar 62.5</i>)
14387F	LEVODOPA + BENSERAZIDE , levodopa 100 mg + benserazide 25 mg capsule, 100 (<i>Madopar 125</i>)
14525L	LEVODOPA + BENSERAZIDE , levodopa 100 mg + benserazide 25 mg modified release capsule, 100 (<i>Madopar HBS</i>)
14551W	LEVODOPA + BENSERAZIDE , levodopa 200 mg + benserazide 50 mg capsule, 100 (<i>Madopar</i>)
14356N	LEVODOPA + BENSERAZIDE , levodopa 50 mg + benserazide 12.5 mg dispersible tablet, 100 (<i>Madopar Rapid 62.5</i>)
14552X	LEVODOPA + BENSERAZIDE , levodopa 100 mg + benserazide 25 mg dispersible tablet, 100 (<i>Madopar Rapid 125</i>)
14455T	LEVODOPA + BENSERAZIDE , levodopa 100 mg + benserazide 25 mg tablet, 100 (<i>Madopar 125</i>)
14428J	LEVODOPA + BENSERAZIDE , levodopa 200 mg + benserazide 50 mg tablet, 100 (<i>Madopar</i>)
14427H	LEVODOPA + CARBIDOPA , levodopa 100 mg + carbidopa 25 mg tablet, 100 (<i>APO-Levodopa/Carbidopa, Kinson, SINADOPA 100/25, Sinemet 100/25</i>)
14322T	LEVODOPA + CARBIDOPA , levodopa 200 mg + carbidopa 50 mg modified release tablet, 100 (<i>Sinemet CR</i>)
14454R	LEVODOPA + CARBIDOPA , levodopa 250 mg + carbidopa 25 mg tablet, 100 (<i>APO-Levodopa/Carbidopa, SINADOPA 250/25, Sinemet</i>)
14456W	LEVODOPA + CARBIDOPA + ENTACAPONE , levodopa 50 mg + carbidopa 12.5 mg + entacapone 200 mg tablet, 100 (<i>Carlevent, L.C.E. Sandoz, LECTEVA, Stalevo 50/12.5/200mg</i>)
14498C	LEVODOPA + CARBIDOPA + ENTACAPONE , levodopa 75 mg + carbidopa 18.75 mg + entacapone 200 mg tablet, 100 (<i>Carlevent, L.C.E. Sandoz, LECTEVA, Stalevo 75/18.75/200mg</i>)
14554B	LEVODOPA + CARBIDOPA + ENTACAPONE , levodopa 100 mg + carbidopa 25 mg + entacapone 200 mg tablet, 100 (<i>Carlevent, L.C.E. Sandoz, LECTEVA, Stalevo 100/25/200mg</i>)
14527N	LEVODOPA + CARBIDOPA + ENTACAPONE , levodopa 125 mg + carbidopa 31.25 mg + entacapone 200 mg tablet, 100 (<i>Carlevent, L.C.E. Sandoz, LECTEVA, Stalevo 125/31.25/200mg</i>)
14357P	LEVODOPA + CARBIDOPA + ENTACAPONE , levodopa 150 mg + carbidopa 37.5 mg + entacapone 200 mg tablet, 100 (<i>Carlevent, L.C.E. Sandoz, LECTEVA, Stalevo 150/37.5/200mg</i>)
14457X	LEVODOPA + CARBIDOPA + ENTACAPONE , levodopa 200 mg + carbidopa 50 mg + entacapone 200 mg tablet, 100 (<i>Carlevent, L.C.E. Sandoz, LECTEVA, Stalevo 200/50/200mg</i>)
14352J	LIQUID PARAFFIN + GLYCEROL + TYLOXAPOL + POLOXAMER-188 + TROMETAMOL HYDROCHLORIDE + TROMETAMOL + CETALKONIUM CHLORIDE , liquid paraffin + glycerol + tyloxapol + poloxamer-188 + trometamol hydrochloride + trometamol + cetalkonium chloride eye drops, 10 mL (<i>Cationorm</i>)
14341T	MACROGOL-3350 , macrogol-3350 1 g/g powder for oral liquid, 510 g (<i>OsmoLax</i>)
14408H	MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE , macrogol-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets (<i>APO-MACROGOL plus ELECTROLYTES, APOHEALTH Macrogol with Electrolytes, Chemists' Own Macrogol with Electrolytes, Macrovic, Molaxole, Movicol</i>)
14366D	MIANSERIN , mianserin hydrochloride 10 mg tablet, 50 (<i>Lumin 10</i>)
14505K	MIANSERIN , mianserin hydrochloride 20 mg tablet, 50 (<i>Lumin 20</i>)
14573B	MIGALASTAT , migalastat 123 mg capsule, 14 (<i>Galafold</i>)
14483G	MINOCYCLINE , minocycline 50 mg tablet, 60 (<i>Akamin 50, Minomycin-50</i>)
14369G	MIRTAZAPINE , mirtazapine 15 mg orally disintegrating tablet, 30 (<i>MIRTANZA ODT</i>)
14507M	MIRTAZAPINE , mirtazapine 15 mg tablet, 30 (<i>APX-Mirtazapine, Axit 15, Blooms The Chemist Mirtazapine, MIRTANZA, MIRTAZAPINE-WGR, Mirtazapine Sandoz</i>)
14370H	MIRTAZAPINE , mirtazapine 30 mg orally disintegrating tablet, 30 (<i>MIRTANZA ODT</i>)
14473R	MIRTAZAPINE , mirtazapine 30 mg tablet, 30 (<i>APX-Mirtazapine, Avanza, Axit 30, Blooms The Chemist Mirtazapine, MIRTANZA, MIRTAZAPINE-WGR, Mirtazapine Sandoz, NOUMED MIRTAZAPINE</i>)
14475W	MIRTAZAPINE , mirtazapine 45 mg orally disintegrating tablet, 30 (<i>MIRTANZA ODT</i>)
14561J	MIRTAZAPINE , mirtazapine 45 mg tablet, 30 (<i>APX-Mirtazapine, Axit 45, Blooms The Chemist Mirtazapine, MIRTANZA, MIRTAZAPINE-WGR, Mirtazapine Sandoz, NOUMED MIRTAZAPINE</i>)
14560H	MOCLOBEMIDE , moclobemide 150 mg tablet, 60 (<i>Amira 150, Aurorix, Clobemix, MOCLOBEMIDE-WGR, Moclobemide Sandoz</i>)
14442D	MOCLOBEMIDE , moclobemide 300 mg tablet, 60 (<i>Amira 300, Aurorix 300 mg, Clobemix, MOCLOBEMIDE-WGR, Moclobemide Sandoz</i>)
14526M	MONTELUKAST , montelukast 4 mg chewable tablet, 28 (<i>MONTELAIR 4, Montelukast APOTEX, Montelukast Lupin, Montelukast Mylan, Montelukast Sandoz 4, Montelukast Viatris</i>)

14553Y **MONTELUKAST**, montelukast 5 mg chewable tablet, 28 (*MONTELAIR 5, Montelukast APOTEX, Montelukast Lupin, Montelukast Mylan, Montelukast Sandoz 5, Montelukast Viatris*)

14306Y **NIZATIDINE**, nizatidine 150 mg capsule, 60 (*Nizac, Tacidine, Tazac*)

14372K **NIZATIDINE**, nizatidine 300 mg capsule, 30 (*Nizac, Tacidine, Tazac*)

14464G **OMEPRAZOLE**, omeprazole 20 mg enteric capsule, 30 (*APO-Omeprazole, Maxor, Omeprazole Sandoz, Pemzo, Pharmacor Omeprazole 20, Probitor*)

14465H **OMEPRAZOLE**, omeprazole 20 mg enteric capsule, 30 (*APO-Omeprazole, Maxor, Omeprazole Sandoz, Pemzo, Pharmacor Omeprazole 20, Probitor*)

14559G **OMEPRAZOLE**, omeprazole 20 mg enteric capsule, 30 (*APO-Omeprazole, Maxor, Omeprazole Sandoz, Pemzo, Pharmacor Omeprazole 20, Probitor*)

14432N **OMEPRAZOLE**, omeprazole 10 mg enteric tablet, 30 (*Losec Tablets*)

14363Y **OMEPRAZOLE**, omeprazole 20 mg enteric tablet, 30 (*Acimax Tablets, Losec Tablets, Omepral, Omeprazole Sandoz*)

14364B **OMEPRAZOLE**, omeprazole 20 mg enteric tablet, 30 (*APO-Omeprazole, Maxor EC Tabs, Ozmep*)

14397R **OMEPRAZOLE**, omeprazole 20 mg enteric tablet, 30 (*Acimax Tablets, Losec Tablets, Omepral, Omeprazole Sandoz*)

14533X **OMEPRAZOLE**, omeprazole 20 mg enteric tablet, 30 (*APO-Omeprazole, Maxor EC Tabs, Ozmep*)

14557E **OMEPRAZOLE**, omeprazole 20 mg enteric tablet, 30 (*Acimax Tablets, Losec Tablets, Omepral, Omeprazole Sandoz*)

14558F **OMEPRAZOLE**, omeprazole 20 mg enteric tablet, 30 (*APO-Omeprazole, Maxor EC Tabs, Ozmep*)

14562K **OXCARBAZEPINE**, oxcarbazepine 150 mg tablet, 100 (*Trileptal*)

14395P **PANTOPRAZOLE**, pantoprazole 40 mg enteric coated granules, 30 sachets (*Somac*)

14466J **PANTOPRAZOLE**, pantoprazole 40 mg enteric coated granules, 30 sachets (*Somac*)

14500E **PANTOPRAZOLE**, pantoprazole 40 mg enteric coated granules, 30 sachets (*Somac*)

14501F **PANTOPRAZOLE**, pantoprazole 20 mg enteric tablet, 30 (*APO-Pantoprazole, BTC Pantoprazole, NOUMED PANTOPRAZOLE, Ozpan, PANTOPRAZOLE-WGR, Panthron, Pantoprazole APOTEX, Pantoprazole Sandoz, Pantoprazole generichealth, Salpraz, Somac, Sozol*)

14330F **PANTOPRAZOLE**, pantoprazole 40 mg enteric tablet, 30 (*APO-Pantoprazole, APX-PANTOPRAZOLE, BTC Pantoprazole, I-Pantoprazole, NOUMED PANTOPRAZOLE, Ozpan, PANTOPRAZOLE-WGR, Panthron, Pantoprazole APOTEX, Pantoprazole Sandoz, Pantoprazole generichealth, Salpraz, Somac, Sozol*)

14362X **PANTOPRAZOLE**, pantoprazole 40 mg enteric tablet, 30 (*APO-Pantoprazole, APX-PANTOPRAZOLE, BTC Pantoprazole, I-Pantoprazole, NOUMED PANTOPRAZOLE, Ozpan, PANTOPRAZOLE-WGR, Panthron, Pantoprazole APOTEX, Pantoprazole Sandoz, Pantoprazole generichealth, Salpraz, Somac, Sozol*)

14394N **PANTOPRAZOLE**, pantoprazole 40 mg enteric tablet, 30 (*APO-Pantoprazole, APX-PANTOPRAZOLE, BTC Pantoprazole, I-Pantoprazole, NOUMED PANTOPRAZOLE, Ozpan, PANTOPRAZOLE-WGR, Panthron, Pantoprazole APOTEX, Pantoprazole Sandoz, Pantoprazole generichealth, Salpraz, Somac, Sozol*)

14353K **PARAFFIN**, paraffin 1 g/g eye ointment, 3.5 g (*Poly Visc*)

14493T **PARAFFIN**, paraffin 1 g/g eye ointment, 2 x 3.5 g (*Poly Visc, Refresh Night Time*)

14367E **PAROXETINE**, paroxetine 20 mg tablet, 30 (*APO-Paroxetine, APX-Paroxetine, Aropax, Blooms The Chemist Paroxetine, Extine 20, Noumed Paroxetine, PAROXETINE-WGR, Paroxetine GH, Paroxetine Sandoz, Paxtine*)

14424E **PERFLUOROHEXYLOCTANE**, perfluorohexyloctane 100% eye drops, 3 mL (*Novatears*)

14355M **PILOCARPINE**, pilocarpine hydrochloride 1% eye drops, 15 mL (*Isopto Carpine*)

14523J **PILOCARPINE**, pilocarpine hydrochloride 2% eye drops, 15 mL (*Isopto Carpine*)

14550T **PILOCARPINE**, pilocarpine hydrochloride 4% eye drops, 15 mL (*Isopto Carpine*)

14421B **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**, polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL (*Optix, Systane*)

14520F **POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**, polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses (*Systane*)

14329E **PRAMIPEXOLE**, pramipexole dihydrochloride monohydrate 250 microgram tablet, 100 (*APO-Pramipexole, Sifrol, Simipex 0.25, Simpral*)

14324X **PRAMIPEXOLE**, pramipexole dihydrochloride monohydrate 375 microgram modified release tablet, 30 (*APO-Pramipexole ER, SIMIPEX XR, Sifrol ER*)

14459B **PRAMIPEXOLE**, pramipexole dihydrochloride monohydrate 750 microgram modified release tablet, 30 (*APO-Pramipexole ER, SIMIPEX XR, Sifrol ER*)

14532W **PRAMIPEXOLE**, pramipexole dihydrochloride monohydrate 1 mg tablet, 100 (*APO-Pramipexole, Sifrol, Simipex 1, Simpral*)

14360T	PRAMIPEXOLE , pramipexole dihydrochloride monohydrate 1.5 mg modified release tablet, 30 (<i>APO-Pramipexole ER, SIMIPEX XR, Sifrol ER</i>)
14556D	PRAMIPEXOLE , pramipexole dihydrochloride monohydrate 2.25 mg modified release tablet, 30 (<i>APO-Pramipexole ER, SIMIPEX XR, Sifrol ER</i>)
14460C	PRAMIPEXOLE , pramipexole dihydrochloride monohydrate 3 mg modified release tablet, 30 (<i>APO-Pramipexole ER, SIMIPEX XR, Sifrol ER</i>)
14461D	PRAMIPEXOLE , pramipexole dihydrochloride monohydrate 3.75 mg modified release tablet, 30 (<i>APO-Pramipexole ER, SIMIPEX XR, Sifrol ER</i>)
14325Y	PRAMIPEXOLE , pramipexole dihydrochloride monohydrate 4.5 mg modified release tablet, 30 (<i>APO-Pramipexole ER, SIMIPEX XR, Sifrol ER</i>)
14392L	PYRIDOSTIGMINE , pyridostigmine bromide 10 mg tablet, 50 (<i>Mestinon</i>)
14529Q	PYRIDOSTIGMINE , pyridostigmine bromide 60 mg tablet, 150 (<i>Mestinon</i>)
14462E	PYRIDOSTIGMINE , pyridostigmine bromide 180 mg modified release tablet, 50 (<i>Mestinon Timespan</i>)
14502G	RABEPRAZOLE , rabeprazole sodium 10 mg enteric tablet, 28 (<i>APO-Rabeprazole, Parbezol, Pariet, RABEPRAZOLE-WGR, Rabeprazole Sandoz</i>)
14396Q	RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30 (<i>APO-Rabeprazole, Noumed Rabeprazole, Parbezol, Pariet, RABEPRAZOLE-WGR, Rabeprazole Mylan, Rabeprazole SUN, Rabeprazole Sandoz, Zabep</i>)
14433P	RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30 (<i>APO-Rabeprazole, Noumed Rabeprazole, Parbezol, Pariet, RABEPRAZOLE-WGR, Rabeprazole Mylan, Rabeprazole SUN, Rabeprazole Sandoz, Zabep</i>)
14463F	RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30 (<i>APO-Rabeprazole, Noumed Rabeprazole, Parbezol, Pariet, RABEPRAZOLE-WGR, Rabeprazole Mylan, Rabeprazole SUN, Rabeprazole Sandoz, Zabep</i>)
14458Y	RASAGILINE , rasagiline 1 mg tablet, 30 (<i>Alziras, Azilect, Pharmacor Rasagiline, RASAGILINE-WGR, Rasagiline Lupin, Rasagiline Sandoz, Rasagiline-Teva</i>)
14474T	REBOXETINE , reboxetine 4 mg tablet, 60 (<i>Edronax</i>)
14429K	RILUZOLE , riluzole 50 mg/10 mL oral liquid, 300 mL (<i>Teglutik</i>)
14393M	RILUZOLE , riluzole 50 mg tablet, 56 (<i>APO-Riluzole, Pharmacor Riluzole, Rilutek, Riluzole Sandoz</i>)
14327C	ROTIGOTINE , rotigotine 2 mg/24 hours patch, 28 (<i>Neupro</i>)
14326B	ROTIGOTINE , rotigotine 4 mg/24 hours patch, 28 (<i>Neupro</i>)
14431M	ROTIGOTINE , rotigotine 6 mg/24 hours patch, 28 (<i>Neupro</i>)
14359R	ROTIGOTINE , rotigotine 8 mg/24 hours patch, 28 (<i>Neupro</i>)
14391K	SAFINAMIDE , safinamide 50 mg tablet, 30 (<i>Xadago</i>)
14528P	SAFINAMIDE , safinamide 100 mg tablet, 30 (<i>Xadago</i>)
14328D	SALMETEROL , salmeterol 50 microgram/actuation powder for inhalation, 60 actuations (<i>Serevent Accuhaler</i>)
14430L	SELEGILINE , selegiline hydrochloride 5 mg tablet, 100 (<i>Eldepryl</i>)
14400X	SERTRALINE , sertraline 50 mg tablet, 30 (<i>APO-Sertraline, Blooms The Chemist Sertraline, Eleva 50, NOUMED SERTRALINE, SERTRALINE-WGR, Sertra 50, Sertraline Sandoz, Sertraline generichealth, Setrona, Zoloft</i>)
14403C	SERTRALINE , sertraline 50 mg tablet, 30 (<i>APO-Sertraline, Blooms The Chemist Sertraline, Eleva 50, NOUMED SERTRALINE, SERTRALINE-WGR, Sertra 50, Sertraline Sandoz, Sertraline generichealth, Zoloft</i>)
14404D	SERTRALINE , sertraline 100 mg tablet, 30 (<i>APO-Sertraline, Blooms The Chemist Sertraline, Eleva 100, NOUMED SERTRALINE, SERTRALINE-WGR, Sertra 100, Sertraline Sandoz, Sertraline generichealth, Zoloft</i>)
14506L	SERTRALINE , sertraline 100 mg tablet, 30 (<i>APO-Sertraline, Blooms The Chemist Sertraline, Eleva 100, NOUMED SERTRALINE, SERTRALINE-WGR, Sertra 100, Sertraline Sandoz, Sertraline generichealth, Setrona, Zoloft</i>)
14426G	SOY LECITHIN + TOCOPHEROL + VITAMIN A , soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% spray, 100 actuations (<i>tearsagain</i>)
14482F	TERIPARATIDE , teriparatide 250 microgram/mL injection, 2.4 mL pen device (<i>Teriparatide Lupin, Terrosa</i>)
14563L	TESTOSTERONE , testosterone 5% (50 mg/mL) cream, 50 mL (<i>AndroForte 5</i>)
14390J	TETRABENAZINE , tetrabenazine 25 mg tablet, 112 (<i>Tetrabenazine SUN, iNova Pharmaceuticals (Australia) Pty Ltd</i>)
14555C	TIOTROPIUM , tiotropium 13 microgram powder for inhalation, 30 capsules (<i>Braltus</i>)
14361W	TIOTROPIUM , tiotropium 18 microgram powder for inhalation, 30 capsules (<i>Spiriva</i>)
14574C	TIOTROPIUM , tiotropium 18 microgram powder for inhalation, 30 capsules (<i>Tiotropium Lupin</i>)
14576E	TIOTROPIUM , tiotropium 18 microgram powder for inhalation, 30 capsules (<i>Tiotropium Lupin</i>)
14323W	TIOTROPIUM , tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations (<i>Spiriva Respimat</i>)
14499D	TIOTROPIUM , tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations (<i>Spiriva Respimat</i>)
14531T	TIOTROPIUM , tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations (<i>Spiriva Respimat</i>)

14530R	TIOTROPIUM + OLODATEROL , tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations (<i>Spiolto Respimat</i>)
14401Y	TRANYLCYPROMINE , tranylcypromine 10 mg tablet, 50 (<i>Parnate</i>)
14549R	TRAVOPROST , travoprost 0.004% eye drops, 2.5 mL (<i>Travatan</i>)
14316L	TRAVOPROST + TIMOLOL , travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL (<i>Duotrav</i>)
14389H	UMECLIDINIUM , umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations (<i>Incruse Ellipta</i>)
14358Q	UMECLIDINIUM + VILANTEROL , umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations (<i>Anoro Ellipta 62.5/25</i>)
14472Q	VENLAFAXINE , venlafaxine 75 mg modified release capsule, 28 (<i>APO-Venlafaxine XR, Efexor-XR, Elaxine SR 75, Enlafax-XR, Sandoz Venlafaxine XR, VENLAFAXINE XR-WGR, Venlafaxine generichealth XR</i>)
14402B	VENLAFAXINE , venlafaxine 150 mg modified release capsule, 28 (<i>APO-Venlafaxine XR, Efexor-XR, Elaxine SR 150, Enlafax-XR, Sandoz Venlafaxine XR, VENLAFAXINE XR-WGR, Venlafaxine generichealth XR</i>)

Addition – Brand

8357W	<i>ACAMPROSATE-WGR, WG</i> – ACAMPROSATE , acamprosate calcium 333 mg enteric tablet, 180
1007B	<i>ACICLOVIR-WGR, WG</i> – ACICLOVIR , aciclovir 200 mg tablet, 90
1052J	<i>ACICLOVIR-WGR, WG</i> – ACICLOVIR , aciclovir 800 mg tablet, 35
9033K	<i>Abrilada, PF</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
13499L	<i>ALENDRONATE-WGR, WG</i> – ALENDRONATE , alendronate 70 mg tablet, 4
8511Y	<i>ALENDRONATE-WGR, WG</i> – ALENDRONATE , alendronate 70 mg tablet, 4
13358C	<i>ALLOPURINOL-WGR, WG</i> – ALLOPURINOL , allopurinol 100 mg tablet, 200
2600W	<i>ALLOPURINOL-WGR, WG</i> – ALLOPURINOL , allopurinol 100 mg tablet, 200
13575L	<i>ALLOPURINOL-WGR, WG</i> – ALLOPURINOL , allopurinol 300 mg tablet, 60
13575L	<i>APO-ALLOPURINOL, TX</i> – ALLOPURINOL , allopurinol 300 mg tablet, 60
2604C	<i>ALLOPURINOL-WGR, WG</i> – ALLOPURINOL , allopurinol 300 mg tablet, 60
2604C	<i>APO-ALLOPURINOL, TX</i> – ALLOPURINOL , allopurinol 300 mg tablet, 60
8594H	<i>AMISULPRIDE-WGR, WG</i> – AMISULPRIDE , amisulpride 100 mg tablet, 30
8595J	<i>AMISULPRIDE-WGR, WG</i> – AMISULPRIDE , amisulpride 200 mg tablet, 60
8596K	<i>AMISULPRIDE-WGR, WG</i> – AMISULPRIDE , amisulpride 400 mg tablet, 60
2417F	<i>AMITRIPTYLINE-WGR, WG</i> – AMITRIPTYLINE , amitriptyline hydrochloride 10 mg tablet, 50
2418G	<i>AMITRIPTYLINE-WGR, WG</i> – AMITRIPTYLINE , amitriptyline hydrochloride 25 mg tablet, 50
13532F	<i>AMLODIPINE-WGR, WG</i> – AMLODIPINE , amlodipine 5 mg tablet, 30
2751T	<i>AMLODIPINE-WGR, WG</i> – AMLODIPINE , amlodipine 5 mg tablet, 30
13562T	<i>AMLODIPINE-WGR, WG</i> – AMLODIPINE , amlodipine 10 mg tablet, 30
2752W	<i>AMLODIPINE-WGR, WG</i> – AMLODIPINE , amlodipine 10 mg tablet, 30
11947T	<i>AMOXICILLIN-WGR, WG</i> – AMOXICILLIN , amoxicillin 500 mg capsule, 20
1889K	<i>AMOXICILLIN-WGR, WG</i> – AMOXICILLIN , amoxicillin 500 mg capsule, 20
3300Q	<i>AMOXICILLIN-WGR, WG</i> – AMOXICILLIN , amoxicillin 500 mg capsule, 20
1887H	<i>AMOXICILLIN-WGR, WG</i> – AMOXICILLIN , amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL
3393N	<i>AMOXICILLIN-WGR, WG</i> – AMOXICILLIN , amoxicillin 250 mg/5 mL powder for oral liquid, 100 mL
11941L	<i>AMOXICILLIN/CLAVULANIC ACID-WGR 500/125, WG</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10
1891M	<i>AMOXICILLIN/CLAVULANIC ACID-WGR 500/125, WG</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10
5008N	<i>AMOXICILLIN/CLAVULANIC ACID-WGR 500/125, WG</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 500 mg + clavulanic acid 125 mg tablet, 10
11933C	<i>AMOXICILLIN/CLAVULANIC ACID-WGR 875/125, WG</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
5006L	<i>AMOXICILLIN/CLAVULANIC ACID-WGR 875/125, WG</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
8254K	<i>AMOXICILLIN/CLAVULANIC ACID-WGR 875/125, WG</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
13858J	<i>ANASTROZOLE-WGR, WG</i> – ANASTROZOLE , anastrozole 1 mg tablet, 30

8179L	<i>ANASTROZOLE-WGR, WG</i> – ANASTROZOLE , anastrozole 1 mg tablet, 30
8717T	<i>ARIPIRAZOLE-WGR, WG</i> – ARIPIRAZOLE , aripiprazole 10 mg tablet, 30
8718W	<i>ARIPIRAZOLE-WGR, WG</i> – ARIPIRAZOLE , aripiprazole 15 mg tablet, 30
8719X	<i>ARIPIRAZOLE-WGR, WG</i> – ARIPIRAZOLE , aripiprazole 20 mg tablet, 30
8720Y	<i>ARIPIRAZOLE-WGR, WG</i> – ARIPIRAZOLE , aripiprazole 30 mg tablet, 30
1081X	<i>ATENOLOL-WGR, WG</i> – ATENOLOL , atenolol 50 mg tablet, 30
13540P	<i>ATENOLOL-WGR, WG</i> – ATENOLOL , atenolol 50 mg tablet, 30
13495G	<i>ATORVASTATIN-WGR, WG</i> – ATORVASTATIN , atorvastatin 10 mg tablet, 30
8213G	<i>ATORVASTATIN-WGR, WG</i> – ATORVASTATIN , atorvastatin 10 mg tablet, 30
13529C	<i>ATORVASTATIN-WGR, WG</i> – ATORVASTATIN , atorvastatin 20 mg tablet, 30
8214H	<i>ATORVASTATIN-WGR, WG</i> – ATORVASTATIN , atorvastatin 20 mg tablet, 30
13468W	<i>ATORVASTATIN-WGR, WG</i> – ATORVASTATIN , atorvastatin 40 mg tablet, 30
8215J	<i>ATORVASTATIN-WGR, WG</i> – ATORVASTATIN , atorvastatin 40 mg tablet, 30
13374X	<i>ATORVASTATIN-WGR, WG</i> – ATORVASTATIN , atorvastatin 80 mg tablet, 30
8521L	<i>ATORVASTATIN-WGR, WG</i> – ATORVASTATIN , atorvastatin 80 mg tablet, 30
2688L	<i>AZATHIOPRINE-WGR, WG</i> – AZATHIOPRINE , azathioprine 25 mg tablet, 100
2687K	<i>AZATHIOPRINE-WGR, WG</i> – AZATHIOPRINE , azathioprine 50 mg tablet, 100
8200N	<i>AZITHROMYCIN-WGR, WG</i> – AZITHROMYCIN , azithromycin 500 mg tablet, 2
8336R	<i>AZITHROMYCIN-WGR, WG</i> – AZITHROMYCIN , azithromycin 500 mg tablet, 2
5551E	<i>BIMATOPROST-WGR, WG</i> – BIMATOPROST , bimatoprost 0.03% eye drops, 3 mL
8620Q	<i>BIMATOPROST-WGR, WG</i> – BIMATOPROST , bimatoprost 0.03% eye drops, 3 mL
13419G	<i>BISOPROLOL-WGR, WG</i> – BISOPROLOL , bisoprolol fumarate 2.5 mg tablet, 28
8604W	<i>BISOPROLOL-WGR, WG</i> – BISOPROLOL , bisoprolol fumarate 2.5 mg tablet, 28
13443M	<i>BISOPROLOL-WGR, WG</i> – BISOPROLOL , bisoprolol fumarate 5 mg tablet, 28
8605X	<i>BISOPROLOL-WGR, WG</i> – BISOPROLOL , bisoprolol fumarate 5 mg tablet, 28
13444N	<i>BISOPROLOL-WGR, WG</i> – BISOPROLOL , bisoprolol fumarate 10 mg tablet, 28
8606Y	<i>BISOPROLOL-WGR, WG</i> – BISOPROLOL , bisoprolol fumarate 10 mg tablet, 28
13592J	<i>CANDESARTAN-WGR, WG</i> – CANDESARTAN , candesartan cilexetil 4 mg tablet, 30
8295N	<i>CANDESARTAN-WGR, WG</i> – CANDESARTAN , candesartan cilexetil 4 mg tablet, 30
13436E	<i>CANDESARTAN-WGR, WG</i> – CANDESARTAN , candesartan cilexetil 8 mg tablet, 30
8296P	<i>CANDESARTAN-WGR, WG</i> – CANDESARTAN , candesartan cilexetil 8 mg tablet, 30
13565Y	<i>CANDESARTAN-WGR, WG</i> – CANDESARTAN , candesartan cilexetil 16 mg tablet, 30
8297Q	<i>CANDESARTAN-WGR, WG</i> – CANDESARTAN , candesartan cilexetil 16 mg tablet, 30
13438G	<i>CANDESARTAN-WGR, WG</i> – CANDESARTAN , candesartan cilexetil 32 mg tablet, 30
8889W	<i>CANDESARTAN-WGR, WG</i> – CANDESARTAN , candesartan cilexetil 32 mg tablet, 30
13391T	<i>CANDESARTAN HCTZ-WGR 16/12.5, WG</i> – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
8504N	<i>CANDESARTAN HCTZ-WGR 16/12.5, WG</i> – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30
13452B	<i>CANDESARTAN HCTZ-WGR 32/12.5, WG</i> – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
9314F	<i>CANDESARTAN HCTZ-WGR 32/12.5, WG</i> – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
13392W	<i>CANDESARTAN HCTZ-WGR 32/25, WG</i> – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
9315G	<i>CANDESARTAN HCTZ-WGR 32/25, WG</i> – CANDESARTAN + HYDROCHLOROTHIAZIDE , candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
13417E	<i>CARVEDILOL-WGR, WG</i> – CARVEDILOL , carvedilol 6.25 mg tablet, 60
8256M	<i>CARVEDILOL-WGR, WG</i> – CARVEDILOL , carvedilol 6.25 mg tablet, 60
13418F	<i>CARVEDILOL-WGR, WG</i> – CARVEDILOL , carvedilol 12.5 mg tablet, 60
8257N	<i>CARVEDILOL-WGR, WG</i> – CARVEDILOL , carvedilol 12.5 mg tablet, 60
13387N	<i>CARVEDILOL-WGR, WG</i> – CARVEDILOL , carvedilol 25 mg tablet, 60

8258P *CARVEDILOL-WGR, WG* – **CARVEDILOL**, carvedilol 25 mg tablet, 60
10778G *CEPHALEXIN-WGR, WG* – **CEFALEXIN**, cefalexin 500 mg capsule, 20
11934D *CEPHALEXIN-WGR, WG* – **CEFALEXIN**, cefalexin 500 mg capsule, 20
3119E *CEPHALEXIN-WGR, WG* – **CEFALEXIN**, cefalexin 500 mg capsule, 20
3318P *CEPHALEXIN-WGR, WG* – **CEFALEXIN**, cefalexin 500 mg capsule, 20
8439E *CELECOXIB-WGR, WG* – **CELECOXIB**, celecoxib 100 mg capsule, 60
8440F *CELECOXIB-WGR, WG* – **CELECOXIB**, celecoxib 200 mg capsule, 30
13883Q *CICLOSPORIN-WGR, WG* – **CICLOSPORIN**, ciclosporin 25 mg capsule, 30
8658Q *CICLOSPORIN-WGR, WG* – **CICLOSPORIN**, ciclosporin 25 mg capsule, 30
13910D *CICLOSPORIN-WGR, WG* – **CICLOSPORIN**, ciclosporin 50 mg capsule, 30
8659R *CICLOSPORIN-WGR, WG* – **CICLOSPORIN**, ciclosporin 50 mg capsule, 30
13911E *CICLOSPORIN-WGR, WG* – **CICLOSPORIN**, ciclosporin 100 mg capsule, 30
8660T *CICLOSPORIN-WGR, WG* – **CICLOSPORIN**, ciclosporin 100 mg capsule, 30
1208N *CIPROFLOXACIN-WGR, WG* – **CIPROFLOXACIN**, ciprofloxacin 250 mg tablet, 14
1209P *CIPROFLOXACIN-WGR, WG* – **CIPROFLOXACIN**, ciprofloxacin 500 mg tablet, 14
1210Q *CIPROFLOXACIN-WGR, WG* – **CIPROFLOXACIN**, ciprofloxacin 750 mg tablet, 14
3138E *CLINDAMYCIN-WGR, WG* – **CLINDAMYCIN**, clindamycin 150 mg capsule, 24
5057E *CLINDAMYCIN-WGR, WG* – **CLINDAMYCIN**, clindamycin 150 mg capsule, 24
1561E *CLOMIPRAMINE-WGR, WG* – **CLOMIPRAMINE**, clomipramine hydrochloride 25 mg tablet, 50
13365K *CLOPIDOGREL-WGR, WG* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28
9354H *CLOPIDOGREL-WGR, WG* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28
10241B *DESVENLAFAXINE-WGR XR, WG* – **DESVENLAFAXINE**, desvenlafaxine 50 mg modified release tablet, 28
10231L *DESVENLAFAXINE-WGR XR, WG* – **DESVENLAFAXINE**, desvenlafaxine 100 mg modified release tablet, 28
3161J *DIAZEPAM-WGR, WG* – **DIAZEPAM**, diazepam 2 mg tablet, 50
5071X *DIAZEPAM-WGR, WG* – **DIAZEPAM**, diazepam 2 mg tablet, 50
3162K *DIAZEPAM-WGR, WG* – **DIAZEPAM**, diazepam 5 mg tablet, 50
5072Y *DIAZEPAM-WGR, WG* – **DIAZEPAM**, diazepam 5 mg tablet, 50
1299J *DICLOFENAC-WGR, WG* – **DICLOFENAC**, diclofenac sodium 25 mg enteric tablet, 50
5076E *DICLOFENAC-WGR, WG* – **DICLOFENAC**, diclofenac sodium 25 mg enteric tablet, 50
1300K *DICLOFENAC-WGR, WG* – **DICLOFENAC**, diclofenac sodium 50 mg enteric tablet, 50
5077F *DICLOFENAC-WGR, WG* – **DICLOFENAC**, diclofenac sodium 50 mg enteric tablet, 50
2532G *DONEPEZIL-WGR, WG* – **DONEPEZIL**, donepezil hydrochloride 5 mg tablet, 28
8495D *DONEPEZIL-WGR, WG* – **DONEPEZIL**, donepezil hydrochloride 5 mg tablet, 28
2479L *DONEPEZIL-WGR, WG* – **DONEPEZIL**, donepezil hydrochloride 10 mg tablet, 28
8496E *DONEPEZIL-WGR, WG* – **DONEPEZIL**, donepezil hydrochloride 10 mg tablet, 28
2711Q *DOXYCYCLINE-WGR, WG* – **DOXYCYCLINE**, doxycycline 50 mg tablet, 25
10779H *DOXYCYCLINE-WGR, WG* – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7
2702F *DOXYCYCLINE-WGR, WG* – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7
2709N *DOXYCYCLINE-WGR, WG* – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7
2714W *DOXYCYCLINE-WGR, WG* – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7
3321T *DOXYCYCLINE-WGR, WG* – **DOXYCYCLINE**, doxycycline 100 mg tablet, 7
13369P *ENALAPRIL-WGR, WG* – **ENALAPRIL**, enalapril maleate 5 mg tablet, 30
1370D *ENALAPRIL-WGR, WG* – **ENALAPRIL**, enalapril maleate 5 mg tablet, 30
13465Q *ENALAPRIL-WGR, WG* – **ENALAPRIL**, enalapril maleate 10 mg tablet, 30
1368B *ENALAPRIL-WGR, WG* – **ENALAPRIL**, enalapril maleate 10 mg tablet, 30
13401H *ENALAPRIL-WGR, WG* – **ENALAPRIL**, enalapril maleate 20 mg tablet, 30
1369C *ENALAPRIL-WGR, WG* – **ENALAPRIL**, enalapril maleate 20 mg tablet, 30
11692J *ESOMEPRAZOLE-WGR, WG* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30
12287Q *ESOMEPRAZOLE-WGR, WG* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30
8600P *ESOMEPRAZOLE-WGR, WG* – **ESOMEPRAZOLE**, esomeprazole 20 mg enteric tablet, 30

8886Q	<i>ESOMEPRAZOLE-WGR, WG – ESOMEPRAZOLE</i> , esomeprazole 20 mg enteric tablet, 30
12283L	<i>ESOMEPRAZOLE-WGR, WG – ESOMEPRAZOLE</i> , esomeprazole 40 mg enteric tablet, 30
3401B	<i>ESOMEPRAZOLE-WGR, WG – ESOMEPRAZOLE</i> , esomeprazole 40 mg enteric tablet, 30
8601Q	<i>ESOMEPRAZOLE-WGR, WG – ESOMEPRAZOLE</i> , esomeprazole 40 mg enteric tablet, 30
10103R	<i>EXEMESTANE-WGR, WG – EXEMESTANE</i> , exemestane 25 mg tablet, 30
13857H	<i>EXEMESTANE-WGR, WG – EXEMESTANE</i> , exemestane 25 mg tablet, 30
14036R	<i>EXEMESTANE-WGR, WG – EXEMESTANE</i> , exemestane 25 mg tablet, 30
8506Q	<i>EXEMESTANE-WGR, WG – EXEMESTANE</i> , exemestane 25 mg tablet, 30
13440J	<i>EZETIMIBE-WGR, WG – EZETIMIBE</i> , ezetimibe 10 mg tablet, 30
8757X	<i>EZETIMIBE-WGR, WG – EZETIMIBE</i> , ezetimibe 10 mg tablet, 30
13385L	<i>EZETIMIBE/SIMVASTATIN-WGR 10/10, WG – EZETIMIBE + SIMVASTATIN</i> , ezetimibe 10 mg + simvastatin 10 mg tablet, 30
9483D	<i>EZETIMIBE/SIMVASTATIN-WGR 10/10, WG – EZETIMIBE + SIMVASTATIN</i> , ezetimibe 10 mg + simvastatin 10 mg tablet, 30
13442L	<i>EZETIMIBE/SIMVASTATIN-WGR 10/20, WG – EZETIMIBE + SIMVASTATIN</i> , ezetimibe 10 mg + simvastatin 20 mg tablet, 30
9484E	<i>EZETIMIBE/SIMVASTATIN-WGR 10/20, WG – EZETIMIBE + SIMVASTATIN</i> , ezetimibe 10 mg + simvastatin 20 mg tablet, 30
13535J	<i>EZETIMIBE/SIMVASTATIN-WGR 10/40, WG – EZETIMIBE + SIMVASTATIN</i> , ezetimibe 10 mg + simvastatin 40 mg tablet, 30
8881K	<i>EZETIMIBE/SIMVASTATIN-WGR 10/40, WG – EZETIMIBE + SIMVASTATIN</i> , ezetimibe 10 mg + simvastatin 40 mg tablet, 30
13595M	<i>EZETIMIBE/SIMVASTATIN-WGR 10/80, WG – EZETIMIBE + SIMVASTATIN</i> , ezetimibe 10 mg + simvastatin 80 mg tablet, 30
8882L	<i>EZETIMIBE/SIMVASTATIN-WGR 10/80, WG – EZETIMIBE + SIMVASTATIN</i> , ezetimibe 10 mg + simvastatin 80 mg tablet, 30
2274Q	<i>FAMCICLOVIR-WGR, WG – FAMCICLOVIR</i> , famciclovir 250 mg tablet, 20
8002E	<i>FAMCICLOVIR-WGR, WG – FAMCICLOVIR</i> , famciclovir 250 mg tablet, 21
8217L	<i>FAMCICLOVIR-WGR, WG – FAMCICLOVIR</i> , famciclovir 250 mg tablet, 56
8896F	<i>FAMCICLOVIR-WGR, WG – FAMCICLOVIR</i> , famciclovir 500 mg tablet, 56
8897G	<i>FAMCICLOVIR-WGR, WG – FAMCICLOVIR</i> , famciclovir 500 mg tablet, 30
13469X	<i>FENOFIBRATE-WGR, WG – FENOFIBRATE</i> , fenofibrate 48 mg tablet, 60
9022W	<i>FENOFIBRATE-WGR, WG – FENOFIBRATE</i> , fenofibrate 48 mg tablet, 60
13587D	<i>FENOFIBRATE-WGR, WG – FENOFIBRATE</i> , fenofibrate 145 mg tablet, 30
9023X	<i>FENOFIBRATE-WGR, WG – FENOFIBRATE</i> , fenofibrate 145 mg tablet, 30
8512B	<i>FLUVOXAMINE-WGR, WG – FLUVOXAMINE</i> , fluvoxamine maleate 50 mg tablet, 30
8174F	<i>FLUVOXAMINE-WGR, WG – FLUVOXAMINE</i> , fluvoxamine maleate 100 mg tablet, 30
13473D	<i>FUROSEMIDE-WGR, WG – FUROSEMIDE</i> , furosemide 20 mg tablet, 100
2414C	<i>FUROSEMIDE-WGR, WG – FUROSEMIDE</i> , furosemide 20 mg tablet, 100
13472C	<i>FUROSEMIDE-WGR, WG – FUROSEMIDE</i> , furosemide 40 mg tablet, 100
2412Y	<i>FUROSEMIDE-WGR, WG – FUROSEMIDE</i> , furosemide 40 mg tablet, 100
1834M	<i>GABAPENTIN-WGR, WG – GABAPENTIN</i> , gabapentin 300 mg capsule, 100
1835N	<i>GABAPENTIN-WGR, WG – GABAPENTIN</i> , gabapentin 400 mg capsule, 100
13848W	<i>GLIMEPIRIDE-WGR, WG – GLIMEPIRIDE</i> , glimepiride 1 mg tablet, 30
8450R	<i>GLIMEPIRIDE-WGR, WG – GLIMEPIRIDE</i> , glimepiride 1 mg tablet, 30
13870B	<i>GLIMEPIRIDE-WGR, WG – GLIMEPIRIDE</i> , glimepiride 2 mg tablet, 30
8451T	<i>GLIMEPIRIDE-WGR, WG – GLIMEPIRIDE</i> , glimepiride 2 mg tablet, 30
14020X	<i>GLIMEPIRIDE-WGR, WG – GLIMEPIRIDE</i> , glimepiride 3 mg tablet, 30
8533D	<i>GLIMEPIRIDE-WGR, WG – GLIMEPIRIDE</i> , glimepiride 3 mg tablet, 30
14055R	<i>GLIMEPIRIDE-WGR, WG – GLIMEPIRIDE</i> , glimepiride 4 mg tablet, 30
8452W	<i>GLIMEPIRIDE-WGR, WG – GLIMEPIRIDE</i> , glimepiride 4 mg tablet, 30
10915L	<i>ARX-IMATINIB, XT – IMATINIB</i> , imatinib 100 mg capsule, 60

10918P *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

10920R *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

10924Y *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

10940T *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

10941W *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

10942X *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

11757T *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

11770L *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

11776T *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

11777W *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

11782D *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

11783E *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

11875B *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

12709X *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

12710Y *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

12722N *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

12759M *ARX-IMATINIB, XT – **IMATINIB***, imatinib 100 mg capsule, 60

13435D *IRBESARTAN-WGR, WG – **IRBESARTAN***, irbesartan 75 mg tablet, 30

8246B *IRBESARTAN-WGR, WG – **IRBESARTAN***, irbesartan 75 mg tablet, 30

13380F *IRBESARTAN-WGR, WG – **IRBESARTAN***, irbesartan 150 mg tablet, 30

8247C *IRBESARTAN-WGR, WG – **IRBESARTAN***, irbesartan 150 mg tablet, 30

13564X *IRBESARTAN-WGR, WG – **IRBESARTAN***, irbesartan 300 mg tablet, 30

8248D *IRBESARTAN-WGR, WG – **IRBESARTAN***, irbesartan 300 mg tablet, 30

13572H *IRBESARTAN HCTZ-WGR 150/12.5, WG – **IRBESARTAN + HYDROCHLOROTHIAZIDE***, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30

8404H *IRBESARTAN HCTZ-WGR 150/12.5, WG – **IRBESARTAN + HYDROCHLOROTHIAZIDE***, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30

13545X *IRBESARTAN HCTZ-WGR 300/12.5, WG – **IRBESARTAN + HYDROCHLOROTHIAZIDE***, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

8405J *IRBESARTAN HCTZ-WGR 300/12.5, WG – **IRBESARTAN + HYDROCHLOROTHIAZIDE***, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30

13446Q *IRBESARTAN HCTZ-WGR 300/25, WG – **IRBESARTAN + HYDROCHLOROTHIAZIDE***, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30

2136K *IRBESARTAN HCTZ-WGR 300/25, WG – **IRBESARTAN + HYDROCHLOROTHIAZIDE***, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30

13461L *ISOSORBIDE MR-WGR, WG – **ISOSORBIDE MONONITRATE***, isosorbide mononitrate 60 mg modified release tablet, 30

1558B *ISOSORBIDE MR-WGR, WG – **ISOSORBIDE MONONITRATE***, isosorbide mononitrate 60 mg modified release tablet, 30

2591J *ISOTRETINOIN-WGR, WG – **ISOTRETINOIN***, isotretinoin 10 mg capsule, 60

2592K *ISOTRETINOIN-WGR, WG – **ISOTRETINOIN***, isotretinoin 20 mg capsule, 60

10012Y *IVABRADINE-WGR, WG – **IVABRADINE***, ivabradine 5 mg tablet, 56

13842M *LAMOTRIGINE-WGR, WG – **LAMOTRIGINE***, lamotrigine 25 mg tablet, 56

2848X *LAMOTRIGINE-WGR, WG – **LAMOTRIGINE***, lamotrigine 25 mg tablet, 56

13975M *LAMOTRIGINE-WGR, WG – **LAMOTRIGINE***, lamotrigine 50 mg tablet, 56

2849Y *LAMOTRIGINE-WGR, WG – **LAMOTRIGINE***, lamotrigine 50 mg tablet, 56

14052N *LAMOTRIGINE-WGR, WG – **LAMOTRIGINE***, lamotrigine 100 mg tablet, 56

2850B *LAMOTRIGINE-WGR, WG – **LAMOTRIGINE***, lamotrigine 100 mg tablet, 56

13843N *LAMOTRIGINE-WGR, WG – **LAMOTRIGINE***, lamotrigine 200 mg tablet, 56

2851C *LAMOTRIGINE-WGR, WG – **LAMOTRIGINE***, lamotrigine 200 mg tablet, 56

5552F *LATANOPROST-WGR, WG – **LATANOPROST***, latanoprost 0.005% eye drops, 2.5 mL

8243W *LATANOPROST-WGR, WG – **LATANOPROST***, latanoprost 0.005% eye drops, 2.5 mL

13940Q	<i>LEFLUNOMIDE-WGR, WG</i> – LEFLUNOMIDE , leflunomide 10 mg tablet, 30
14068K	<i>LEFLUNOMIDE-WGR, WG</i> – LEFLUNOMIDE , leflunomide 10 mg tablet, 30
5449T	<i>LEFLUNOMIDE-WGR, WG</i> – LEFLUNOMIDE , leflunomide 10 mg tablet, 30
8374R	<i>LEFLUNOMIDE-WGR, WG</i> – LEFLUNOMIDE , leflunomide 10 mg tablet, 30
13998R	<i>LEFLUNOMIDE-WGR, WG</i> – LEFLUNOMIDE , leflunomide 20 mg tablet, 30
14069L	<i>LEFLUNOMIDE-WGR, WG</i> – LEFLUNOMIDE , leflunomide 20 mg tablet, 30
5450W	<i>LEFLUNOMIDE-WGR, WG</i> – LEFLUNOMIDE , leflunomide 20 mg tablet, 30
8375T	<i>LEFLUNOMIDE-WGR, WG</i> – LEFLUNOMIDE , leflunomide 20 mg tablet, 30
13411W	<i>LERCANIDIPINE-WGR, WG</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
8534E	<i>LERCANIDIPINE-WGR, WG</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
13412X	<i>LERCANIDIPINE-WGR, WG</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
8679T	<i>LERCANIDIPINE-WGR, WG</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
13939P	<i>LETROZOLE-WGR, WG</i> – LETROZOLE , letrozole 2.5 mg tablet, 30
8245Y	<i>LETROZOLE-WGR, WG</i> – LETROZOLE , letrozole 2.5 mg tablet, 30
13992K	<i>LEVETIRACETAM-WGR, WG</i> – LEVETIRACETAM , levetiracetam 250 mg tablet, 60
8654L	<i>LEVETIRACETAM-WGR, WG</i> – LEVETIRACETAM , levetiracetam 250 mg tablet, 60
14034P	<i>LEVETIRACETAM-WGR, WG</i> – LEVETIRACETAM , levetiracetam 500 mg tablet, 60
8655M	<i>LEVETIRACETAM-WGR, WG</i> – LEVETIRACETAM , levetiracetam 500 mg tablet, 60
13937M	<i>LEVETIRACETAM-WGR, WG</i> – LEVETIRACETAM , levetiracetam 1 g tablet, 60
8656N	<i>LEVETIRACETAM-WGR, WG</i> – LEVETIRACETAM , levetiracetam 1 g tablet, 60
1394J	<i>LEVETH 150/30 ED, WG</i> – LEVONORGESTREL + ETHINYLESTRADIOL , levonorgestrel 150 microgram + ethinylestradiol 30 microgram tablet [21] (&) inert substance tablet [7], 4 x 28
13583X	<i>LISINAPRIL-WGR, WG</i> – LISINAPRIL , lisinopril 5 mg tablet, 30
2456G	<i>LISINAPRIL-WGR, WG</i> – LISINAPRIL , lisinopril 5 mg tablet, 30
13584Y	<i>LISINAPRIL-WGR, WG</i> – LISINAPRIL , lisinopril 10 mg tablet, 30
2457H	<i>LISINAPRIL-WGR, WG</i> – LISINAPRIL , lisinopril 10 mg tablet, 30
13402J	<i>LISINAPRIL-WGR, WG</i> – LISINAPRIL , lisinopril 20 mg tablet, 30
2458J	<i>LISINAPRIL-WGR, WG</i> – LISINAPRIL , lisinopril 20 mg tablet, 30
10526B	<i>LURASIDONE-WGR, WG</i> – LURASIDONE , lurasidone hydrochloride 40 mg tablet, 30
10529E	<i>LURASIDONE-WGR, WG</i> – LURASIDONE , lurasidone hydrochloride 80 mg tablet, 30
8887R	<i>MELOXICAM-WGR, WG</i> – MELOXICAM , meloxicam 7.5 mg capsule, 30
8888T	<i>MELOXICAM-WGR, WG</i> – MELOXICAM , meloxicam 15 mg capsule, 30
8561N	<i>MELOXICAM-WGR, WG</i> – MELOXICAM , meloxicam 7.5 mg tablet, 30
8562P	<i>MELOXICAM-WGR, WG</i> – MELOXICAM , meloxicam 15 mg tablet, 30
13899M	<i>METFORMIN-WGR XR, WG</i> – METFORMIN , metformin hydrochloride 500 mg modified release tablet, 120
13976N	<i>METFORMIN-WGR, WG</i> – METFORMIN , metformin hydrochloride 500 mg tablet, 100
2430X	<i>METFORMIN-WGR, WG</i> – METFORMIN , metformin hydrochloride 500 mg tablet, 100
9435N	<i>METFORMIN-WGR XR, WG</i> – METFORMIN , metformin hydrochloride 500 mg modified release tablet, 120
13952H	<i>Diaformin Viatris, MQ</i> – METFORMIN , metformin hydrochloride 850 mg tablet, 60
13952H	<i>METFORMIN-WGR, WG</i> – METFORMIN , metformin hydrochloride 850 mg tablet, 60
1801T	<i>Diaformin Viatris, MQ</i> – METFORMIN , metformin hydrochloride 850 mg tablet, 60
1801T	<i>METFORMIN-WGR, WG</i> – METFORMIN , metformin hydrochloride 850 mg tablet, 60
13847T	<i>METFORMIN-WGR XR, WG</i> – METFORMIN , metformin hydrochloride 1 g modified release tablet, 60
14056T	<i>Diaformin Viatris, MQ</i> – METFORMIN , metformin hydrochloride 1 g tablet, 90
3439B	<i>METFORMIN-WGR XR, WG</i> – METFORMIN , metformin hydrochloride 1 g modified release tablet, 60
8607B	<i>Diaformin Viatris, MQ</i> – METFORMIN , metformin hydrochloride 1 g tablet, 90
1207M	<i>METOCLOPRAMIDE-WGR, WG</i> – METOCLOPRAMIDE , metoclopramide hydrochloride 10 mg tablet, 25
5151D	<i>METOCLOPRAMIDE-WGR, WG</i> – METOCLOPRAMIDE , metoclopramide hydrochloride 10 mg tablet, 25
1324Q	<i>METOPROLOL-WGR, WG</i> – METOPROLOL TARTRATE , METOPROLOL TARTRATE Tablet 50 mg, 100
13598Q	<i>METOPROLOL-WGR, WG</i> – METOPROLOL TARTRATE , METOPROLOL TARTRATE Tablet 50 mg, 100
1325R	<i>METOPROLOL-WGR, WG</i> – METOPROLOL TARTRATE , METOPROLOL TARTRATE Tablet 100 mg, 60

13541Q *METOPROLOL-WGR, WG* – **METOPROLOL TARTRATE**, METOPROLOL TARTRATE Tablet 100 mg, 60

9365X *MIRTAZAPINE-WGR, WG* – **MIRTAZAPINE**, mirtazapine 15 mg tablet, 30

8513C *MIRTAZAPINE-WGR, WG* – **MIRTAZAPINE**, mirtazapine 30 mg tablet, 30

8883M *MIRTAZAPINE-WGR, WG* – **MIRTAZAPINE**, mirtazapine 45 mg tablet, 30

1900B *MOCLOBEMIDE-WGR, WG* – **MOCLOBEMIDE**, moclobemide 150 mg tablet, 60

8003F *MOCLOBEMIDE-WGR, WG* – **MOCLOBEMIDE**, moclobemide 300 mg tablet, 60

8816B *MODAFINIL-WGR, WG* – **MODAFINIL**, modafinil 100 mg tablet, 60

8628D *Montelukast Viatris, AL* – **MONTELUKAST**, montelukast 5 mg chewable tablet, 28

13579Q *MOXONIDINE-WGR, WG* – **MOXONIDINE**, moxonidine 200 microgram tablet, 30

9019Q *MOXONIDINE-WGR, WG* – **MOXONIDINE**, moxonidine 200 microgram tablet, 30

13552G *MOXONIDINE-WGR, WG* – **MOXONIDINE**, moxonidine 400 microgram tablet, 30

9020R *MOXONIDINE-WGR, WG* – **MOXONIDINE**, moxonidine 400 microgram tablet, 30

3381Y *OLANZAPINE ODT-WGR, WG* – **OLANZAPINE**, olanzapine 5 mg orally disintegrating tablet, 28

3382B *OLANZAPINE ODT-WGR, WG* – **OLANZAPINE**, olanzapine 10 mg orally disintegrating tablet, 28

3384D *OLANZAPINE ODT-WGR, WG* – **OLANZAPINE**, olanzapine 15 mg orally disintegrating tablet, 28

3385E *OLANZAPINE ODT-WGR, WG* – **OLANZAPINE**, olanzapine 20 mg orally disintegrating tablet, 28

13505T *OLMESARTAN-WGR, WG* – **OLMESARTAN**, olmesartan medoxomil 20 mg tablet, 30

2147B *OLMESARTAN-WGR, WG* – **OLMESARTAN**, olmesartan medoxomil 20 mg tablet, 30

13533G *OLMESARTAN-WGR, WG* – **OLMESARTAN**, olmesartan medoxomil 40 mg tablet, 30

2148C *OLMESARTAN-WGR, WG* – **OLMESARTAN**, olmesartan medoxomil 40 mg tablet, 30

13449W *APO-OLMESARTAN/AMLODIPINE 20/5, TY* – **OLMESARTAN + AMLODIPINE**, olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30

13449W *OLMESARTAN AMLODIPINE-WGR 20/5, WG* – **OLMESARTAN + AMLODIPINE**, olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30

5292M *APO-OLMESARTAN/AMLODIPINE 20/5, TY* – **OLMESARTAN + AMLODIPINE**, olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30

5292M *OLMESARTAN AMLODIPINE-WGR 20/5, WG* – **OLMESARTAN + AMLODIPINE**, olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30

13964Y *OLMESARTAN AMLODIPINE-WGR 40/5, WG* – **OLMESARTAN + AMLODIPINE**, olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30

5293N *OLMESARTAN AMLODIPINE-WGR 40/5, WG* – **OLMESARTAN + AMLODIPINE**, olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30

13943W *OLMESARTAN AMLODIPINE-WGR 40/10, WG* – **OLMESARTAN + AMLODIPINE**, olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30

5294P *OLMESARTAN AMLODIPINE-WGR 40/10, WG* – **OLMESARTAN + AMLODIPINE**, olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30

13447R *OLMESARTAN HCTZ-WGR 20/12.5, WG* – **OLMESARTAN + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

2161R *OLMESARTAN HCTZ-WGR 20/12.5, WG* – **OLMESARTAN + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30

13601W *OLMESARTAN HCTZ-WGR 40/12.5, WG* – **OLMESARTAN + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30

2166B *OLMESARTAN HCTZ-WGR 40/12.5, WG* – **OLMESARTAN + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30

13602X *OLMESARTAN HCTZ-WGR 40/25, WG* – **OLMESARTAN + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30

2170F *OLMESARTAN HCTZ-WGR 40/25, WG* – **OLMESARTAN + HYDROCHLOROTHIAZIDE**, olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30

1594X *ONDANSETRON-WGR, WG* – **ONDANSETRON**, ondansetron 4 mg tablet, 10

5470X *ONDANSETRON ODT-WGR, WG* – **ONDANSETRON**, ondansetron 4 mg orally disintegrating tablet, 4

5472B *ONDANSETRON ODT-WGR, WG* – **ONDANSETRON**, ondansetron 4 mg orally disintegrating tablet, 10

8224W *ONDANSETRON-WGR, WG* – **ONDANSETRON**, ondansetron 4 mg tablet, 4

1595Y *ONDANSETRON-WGR, WG* – **ONDANSETRON**, ondansetron 8 mg tablet, 10

5471Y *ONDANSETRON ODT-WGR, WG* – **ONDANSETRON**, ondansetron 8 mg orally disintegrating tablet, 4

5473C	<i>ONDANSETRON ODT-WGR, WG</i> – ONDANSETRON , ondansetron 8 mg orally disintegrating tablet, 10
8225X	<i>ONDANSETRON-WGR, WG</i> – ONDANSETRON , ondansetron 8 mg tablet, 4
3133X	<i>OXAZEPAM-WGR, WG</i> – OXAZEPAM , oxazepam 30 mg tablet, 25
3135B	<i>OXAZEPAM-WGR, WG</i> – OXAZEPAM , oxazepam 30 mg tablet, 25
5193H	<i>OXAZEPAM-WGR, WG</i> – OXAZEPAM , oxazepam 30 mg tablet, 25
8399C	<i>PANTOPRAZOLE-WGR, WG</i> – PANTOPRAZOLE , pantoprazole 20 mg enteric tablet, 30
11681T	<i>PANTOPRAZOLE-WGR, WG</i> – PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30
12277E	<i>PANTOPRAZOLE-WGR, WG</i> – PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30
8007K	<i>PANTOPRAZOLE-WGR, WG</i> – PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30
8008L	<i>PANTOPRAZOLE-WGR, WG</i> – PANTOPRAZOLE , pantoprazole 40 mg enteric tablet, 30
2242B	<i>PAROXETINE-WGR, WG</i> – PAROXETINE , paroxetine 20 mg tablet, 30
13404L	<i>PERINDOPRIL-WGR, WG</i> – PERINDOPRIL , perindopril erbumine 2 mg tablet, 30
3050M	<i>PERINDOPRIL-WGR, WG</i> – PERINDOPRIL , perindopril erbumine 2 mg tablet, 30
13494F	<i>Perindopril Arginine-WGR, WG</i> – PERINDOPRIL , perindopril arginine 2.5 mg tablet, 30
9006B	<i>Perindopril Arginine-WGR, WG</i> – PERINDOPRIL , perindopril arginine 2.5 mg tablet, 30
13371R	<i>PERINDOPRIL-WGR, WG</i> – PERINDOPRIL , perindopril erbumine 4 mg tablet, 30
3051N	<i>PERINDOPRIL-WGR, WG</i> – PERINDOPRIL , perindopril erbumine 4 mg tablet, 30
13585B	<i>Perindopril Arginine-WGR, WG</i> – PERINDOPRIL , perindopril arginine 5 mg tablet, 30
9007C	<i>Perindopril Arginine-WGR, WG</i> – PERINDOPRIL , perindopril arginine 5 mg tablet, 30
13372T	<i>PERINDOPRIL-WGR, WG</i> – PERINDOPRIL , perindopril erbumine 8 mg tablet, 30
8704D	<i>PERINDOPRIL-WGR, WG</i> – PERINDOPRIL , perindopril erbumine 8 mg tablet, 30
13555K	<i>Perindopril Arginine-WGR, WG</i> – PERINDOPRIL , perindopril arginine 10 mg tablet, 30
9008D	<i>Perindopril Arginine-WGR, WG</i> – PERINDOPRIL , perindopril arginine 10 mg tablet, 30
13476G	<i>PERINDOPRIL/INDAPAMIDE-WGR 4/1.25, WG</i> – PERINDOPRIL + INDAPAMIDE , perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30
8449Q	<i>PERINDOPRIL/INDAPAMIDE-WGR 4/1.25, WG</i> – PERINDOPRIL + INDAPAMIDE , perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30
13898L	<i>ARX-PIOGLITAZONE, XT</i> – PIOGLITAZONE , pioglitazone 15 mg tablet, 28
8694N	<i>ARX-PIOGLITAZONE, XT</i> – PIOGLITAZONE , pioglitazone 15 mg tablet, 28
10460M	<i>POSACONAZOLE-WGR, WG</i> – POSACONAZOLE , posaconazole 100 mg modified release tablet, 24
13496H	<i>PRAVASTATIN-WGR, WG</i> – PRAVASTATIN , pravastatin sodium 10 mg tablet, 30
2833D	<i>PRAVASTATIN-WGR, WG</i> – PRAVASTATIN , pravastatin sodium 10 mg tablet, 30
13497J	<i>PRAVASTATIN-WGR, WG</i> – PRAVASTATIN , pravastatin sodium 20 mg tablet, 30
2834E	<i>PRAVASTATIN-WGR, WG</i> – PRAVASTATIN , pravastatin sodium 20 mg tablet, 30
13432Y	<i>PRAVASTATIN-WGR, WG</i> – PRAVASTATIN , pravastatin sodium 40 mg tablet, 30
8197K	<i>PRAVASTATIN-WGR, WG</i> – PRAVASTATIN , pravastatin sodium 40 mg tablet, 30
2348N	<i>PREGABALIN-WGR, WG</i> – PREGABALIN , pregabalin 25 mg capsule, 56
2335X	<i>PREGABALIN-WGR, WG</i> – PREGABALIN , pregabalin 75 mg capsule, 56
2355Y	<i>PREGABALIN-WGR, WG</i> – PREGABALIN , pregabalin 150 mg capsule, 56
2363J	<i>PREGABALIN-WGR, WG</i> – PREGABALIN , pregabalin 300 mg capsule, 56
2893G	<i>PROCHLORPERAZINE-WGR, WG</i> – PROCHLORPERAZINE , prochlorperazine maleate 5 mg tablet, 25
5205Y	<i>PROCHLORPERAZINE-WGR, WG</i> – PROCHLORPERAZINE , prochlorperazine maleate 5 mg tablet, 25
13386M	<i>PROPRANOLOL-WGR, WG</i> – PROPRANOLOL , propranolol hydrochloride 10 mg tablet, 100
2565B	<i>PROPRANOLOL-WGR, WG</i> – PROPRANOLOL , propranolol hydrochloride 10 mg tablet, 100
13542R	<i>PROPRANOLOL-WGR, WG</i> – PROPRANOLOL , propranolol hydrochloride 40 mg tablet, 100
2566C	<i>PROPRANOLOL-WGR, WG</i> – PROPRANOLOL , propranolol hydrochloride 40 mg tablet, 100
8507R	<i>RABEPRAZOLE-WGR, WG</i> – RABEPRAZOLE , rabeprazole sodium 10 mg enteric tablet, 28
11670F	<i>RABEPRAZOLE-WGR, WG</i> – RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30
12286P	<i>RABEPRAZOLE-WGR, WG</i> – RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30
8508T	<i>RABEPRAZOLE-WGR, WG</i> – RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30
8509W	<i>RABEPRAZOLE-WGR, WG</i> – RABEPRAZOLE , rabeprazole sodium 20 mg enteric tablet, 30

13430W *RAMIPRIL-WGR, WG* – **RAMIPRIL**, ramipril 10 mg capsule, 30

8470T *RAMIPRIL-WGR, WG* – **RAMIPRIL**, ramipril 10 mg capsule, 30

13582W *RAMIPRIL-WGR, WG* – **RAMIPRIL**, ramipril 1.25 mg tablet, 30

1944H *RAMIPRIL-WGR, WG* – **RAMIPRIL**, ramipril 1.25 mg tablet, 30

13466R *RAMIPRIL-WGR, WG* – **RAMIPRIL**, ramipril 2.5 mg tablet, 30

1945J *RAMIPRIL-WGR, WG* – **RAMIPRIL**, ramipril 2.5 mg tablet, 30

13526X *RAMIPRIL-WGR, WG* – **RAMIPRIL**, ramipril 5 mg tablet, 30

13526X *Ramipril Viatrix, AL* – **RAMIPRIL**, ramipril 5 mg tablet, 30

1946K *RAMIPRIL-WGR, WG* – **RAMIPRIL**, ramipril 5 mg tablet, 30

1946K *Ramipril Viatrix, AL* – **RAMIPRIL**, ramipril 5 mg tablet, 30

1316G *RAMIPRIL TABS-WGR, WG* – **RAMIPRIL**, ramipril 10 mg tablet, 30

13368N *RAMIPRIL TABS-WGR, WG* – **RAMIPRIL**, ramipril 10 mg tablet, 30

1952R *RASAGILINE-WGR, WG* – **RASAGILINE**, rasagiline 1 mg tablet, 30

13459J *RISEDRONATE-WGR, WG* – **RISEDRONATE**, risedronate sodium 35 mg tablet, 4

8621R *RISEDRONATE-WGR, WG* – **RISEDRONATE**, risedronate sodium 35 mg tablet, 4

11874Y *Risperidone Lupin, GQ* – **RISPERIDONE**, risperidone 1 mg/mL oral liquid, 100 mL

11882J *Risperidone Lupin, GQ* – **RISPERIDONE**, risperidone 1 mg/mL oral liquid, 100 mL

8100H *Risperidone Lupin, GQ* – **RISPERIDONE**, risperidone 1 mg/mL oral liquid, 100 mL

9293D *Risperidone Lupin, GQ* – **RISPERIDONE**, risperidone 1 mg/mL oral liquid, 100 mL

10551H *RIZATRIPTAN ODT-WGR, WG* – **RIZATRIPTAN**, rizatriptan 10 mg orally disintegrating tablet, 2

13406N *APO-ROSUVASTATIN, TX* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

13406N *ROSUVASTATIN-WGR, WG* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

2606E *APO-ROSUVASTATIN, TX* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

2606E *ROSUVASTATIN-WGR, WG* – **ROSUVASTATIN**, rosuvastatin 5 mg tablet, 30

13586C *ROSUVASTATIN-WGR, WG* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

2628H *ROSUVASTATIN-WGR, WG* – **ROSUVASTATIN**, rosuvastatin 10 mg tablet, 30

13588E *ROSUVASTATIN-WGR, WG* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

2574L *ROSUVASTATIN-WGR, WG* – **ROSUVASTATIN**, rosuvastatin 20 mg tablet, 30

13589F *ROSUVASTATIN-WGR, WG* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

2594M *ROSUVASTATIN-WGR, WG* – **ROSUVASTATIN**, rosuvastatin 40 mg tablet, 30

12001P *ROXITHROMYCIN-WGR, WG* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

1760P *ROXITHROMYCIN-WGR, WG* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

5260W *ROXITHROMYCIN-WGR, WG* – **ROXITHROMYCIN**, roxithromycin 150 mg tablet, 10

11993F *ROXITHROMYCIN-WGR, WG* – **ROXITHROMYCIN**, roxithromycin 300 mg tablet, 5

5261X *ROXITHROMYCIN-WGR, WG* – **ROXITHROMYCIN**, roxithromycin 300 mg tablet, 5

8016X *ROXITHROMYCIN-WGR, WG* – **ROXITHROMYCIN**, roxithromycin 300 mg tablet, 5

2236Q *SERTRALINE-WGR, WG* – **SERTRALINE**, sertraline 50 mg tablet, 30

8836C *SERTRALINE-WGR, WG* – **SERTRALINE**, sertraline 50 mg tablet, 30

2237R *SERTRALINE-WGR, WG* – **SERTRALINE**, sertraline 100 mg tablet, 30

8837D *SERTRALINE-WGR, WG* – **SERTRALINE**, sertraline 100 mg tablet, 30

8398B *SOTALOL-WGR, WG* – **SOTALOL**, sotalol hydrochloride 80 mg tablet, 60

2043M *SOTALOL-WGR, WG* – **SOTALOL**, sotalol hydrochloride 160 mg tablet, 60

1849H *SUMATRIPTAN-WGR, WG* – **SUMATRIPTAN**, sumatriptan 50 mg tablet, 4

13437F *TELMISARTAN-WGR, WG* – **TELMISARTAN**, telmisartan 40 mg tablet, 28

8355R *TELMISARTAN-WGR, WG* – **TELMISARTAN**, telmisartan 40 mg tablet, 28

13593K *TELMISARTAN-WGR, WG* – **TELMISARTAN**, telmisartan 80 mg tablet, 28

8356T *TELMISARTAN-WGR, WG* – **TELMISARTAN**, telmisartan 80 mg tablet, 28

13546Y *TELMISARTAN HCTZ-WGR 40/12.5, WG* – **TELMISARTAN + HYDROCHLOROTHIAZIDE**, telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28

8622T *TELMISARTAN HCTZ-WGR 40/12.5, WG* – **TELMISARTAN + HYDROCHLOROTHIAZIDE**, telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28

13574K	<i>TELMISARTAN HCTZ-WGR 80/12.5, WG</i> – TELMISARTAN + HYDROCHLOROTHIAZIDE , telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28
8623W	<i>TELMISARTAN HCTZ-WGR 80/12.5, WG</i> – TELMISARTAN + HYDROCHLOROTHIAZIDE , telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28
13607E	<i>TELMISARTAN HCTZ-WGR 80/25, WG</i> – TELMISARTAN + HYDROCHLOROTHIAZIDE , telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28
9381R	<i>TELMISARTAN HCTZ-WGR 80/25, WG</i> – TELMISARTAN + HYDROCHLOROTHIAZIDE , telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28
2088X	<i>TEMAZEPAM-WGR, WG</i> – TEMAZEPAM , temazepam 10 mg tablet, 25
2089Y	<i>TEMAZEPAM-WGR, WG</i> – TEMAZEPAM , temazepam 10 mg tablet, 25
5221T	<i>TEMAZEPAM-WGR, WG</i> – TEMAZEPAM , temazepam 10 mg tablet, 25
2285G	<i>TERBINAFINE-WGR, WG</i> – TERBINAFINE , terbinafine 250 mg tablet, 42
2804N	<i>TERBINAFINE-WGR, WG</i> – TERBINAFINE , terbinafine 250 mg tablet, 42
13969F	<i>TOPIRAMATE-WGR, WG</i> – TOPIRAMATE , topiramate 25 mg tablet, 60
8163P	<i>TOPIRAMATE-WGR, WG</i> – TOPIRAMATE , topiramate 25 mg tablet, 60
13913G	<i>TOPIRAMATE-WGR, WG</i> – TOPIRAMATE , topiramate 50 mg tablet, 60
8164Q	<i>TOPIRAMATE-WGR, WG</i> – TOPIRAMATE , topiramate 50 mg tablet, 60
14008G	<i>TOPIRAMATE-WGR, WG</i> – TOPIRAMATE , topiramate 100 mg tablet, 60
8165R	<i>TOPIRAMATE-WGR, WG</i> – TOPIRAMATE , topiramate 100 mg tablet, 60
14009H	<i>TOPIRAMATE-WGR, WG</i> – TOPIRAMATE , topiramate 200 mg tablet, 60
8166T	<i>TOPIRAMATE-WGR, WG</i> – TOPIRAMATE , topiramate 200 mg tablet, 60
12008B	<i>TRAMADOL-WGR, WG</i> – TRAMADOL , tramadol hydrochloride 50 mg capsule, 20
12024W	<i>TRAMADOL-WGR, WG</i> – TRAMADOL , tramadol hydrochloride 50 mg capsule, 20
5232J	<i>TRAMADOL-WGR, WG</i> – TRAMADOL , tramadol hydrochloride 50 mg capsule, 20
8455B	<i>TRAMADOL-WGR, WG</i> – TRAMADOL , tramadol hydrochloride 50 mg capsule, 20
8523N	<i>TRAMADOL-WGR SR, WG</i> – TRAMADOL , tramadol hydrochloride 100 mg modified release tablet, 20
8524P	<i>TRAMADOL-WGR SR, WG</i> – TRAMADOL , tramadol hydrochloride 150 mg modified release tablet, 20
8525Q	<i>TRAMADOL-WGR SR, WG</i> – TRAMADOL , tramadol hydrochloride 200 mg modified release tablet, 20
10785P	<i>TRIMETHOPRIM-WGR, WG</i> – TRIMETHOPRIM , trimethoprim 300 mg tablet, 7
2666H	<i>TRIMETHOPRIM-WGR, WG</i> – TRIMETHOPRIM , trimethoprim 300 mg tablet, 7
2922T	<i>TRIMETHOPRIM-WGR, WG</i> – TRIMETHOPRIM , trimethoprim 300 mg tablet, 7
5480K	<i>VALACICLOVIR-WGR, WG</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30
8064K	<i>VALACICLOVIR-WGR, WG</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 42
8133C	<i>VALACICLOVIR-WGR, WG</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 10
8134D	<i>VALACICLOVIR-WGR, WG</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30
8868R	<i>VENLAFAXINE XR-WGR, WG</i> – VENLAFAXINE , venlafaxine 37.5 mg modified release capsule, 28
8301X	<i>VENLAFAXINE XR-WGR, WG</i> – VENLAFAXINE , venlafaxine 75 mg modified release capsule, 28
8302Y	<i>VENLAFAXINE XR-WGR, WG</i> – VENLAFAXINE , venlafaxine 150 mg modified release capsule, 28

Addition – Equivalence Indicator

1892N	<i>Curam, SZ</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL
5009P	<i>Curam, SZ</i> – AMOXICILLIN + CLAVULANIC ACID , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL
8201P	<i>Zithromax, PF</i> – AZITHROMYCIN , azithromycin 200 mg/5 mL powder for oral liquid, 15 mL

Addition – Note

12351C	ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (<i>Amgevita</i>)
12436M	ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe (<i>Amgevita</i>)
14253E	ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Abrilada</i>)
14274G	ADALIMUMAB , adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes (<i>Abrilada</i>)
1892N	AMOXICILLIN + CLAVULANIC ACID , amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL (<i>Curam</i>)

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- 5009P **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL (*Curam*)
- 8201P **AZITHROMYCIN**, azithromycin 200 mg/5 mL powder for oral liquid, 15 mL (*Zithromax*)

Deletions

Deletion – Item

- 8401E **FOSINOPRIL + HYDROCHLOROTHIAZIDE**, fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30 (*Fosetic 20/12.5*)
- 13736Y **METHYLPREDNISOLONE**, methylprednisolone (as sodium succinate) 40 mg powder for injection, 1 vial (*Solu-Medrone*)

Deletion – Brand

- 13532F *BTC Amlodipine, JB* – **AMLODIPINE**, amlodipine 5 mg tablet, 30
- 2751T *BTC Amlodipine, JB* – **AMLODIPINE**, amlodipine 5 mg tablet, 30
- 13562T *BTC Amlodipine, JB* – **AMLODIPINE**, amlodipine 10 mg tablet, 30
- 2752W *BTC Amlodipine, JB* – **AMLODIPINE**, amlodipine 10 mg tablet, 30
- 11933C *AlphaClav Duo Forte, AF* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
- 5006L *AlphaClav Duo Forte, AF* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
- 8254K *AlphaClav Duo Forte, AF* – **AMOXICILLIN + CLAVULANIC ACID**, amoxicillin 875 mg + clavulanic acid 125 mg tablet, 10
- 13495G *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30
- 8213G *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 10 mg tablet, 30
- 13529C *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30
- 8214H *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 20 mg tablet, 30
- 13468W *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30
- 8215J *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 40 mg tablet, 30
- 13374X *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 80 mg tablet, 30
- 8521L *Blooms the Chemist Atorvastatin, IB* – **ATORVASTATIN**, atorvastatin 80 mg tablet, 30
- 13592J *Blooms the Chemist Candesartan, IB* – **CANDESARTAN**, candesartan cilexetil 4 mg tablet, 30
- 8295N *Blooms the Chemist Candesartan, IB* – **CANDESARTAN**, candesartan cilexetil 4 mg tablet, 30
- 13436E *Blooms the Chemist Candesartan, IB* – **CANDESARTAN**, candesartan cilexetil 8 mg tablet, 30
- 8296P *Blooms the Chemist Candesartan, IB* – **CANDESARTAN**, candesartan cilexetil 8 mg tablet, 30
- 13565Y *Blooms the Chemist Candesartan, IB* – **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30
- 8297Q *Blooms the Chemist Candesartan, IB* – **CANDESARTAN**, candesartan cilexetil 16 mg tablet, 30
- 13438G *Blooms the Chemist Candesartan, IB* – **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30
- 8889W *Blooms the Chemist Candesartan, IB* – **CANDESARTAN**, candesartan cilexetil 32 mg tablet, 30
- 13452B *Blooms the Chemist Candesartan HCTZ 32/12.5, IB* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 9314F *Blooms the Chemist Candesartan HCTZ 32/12.5, IB* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30
- 13392W *Blooms the Chemist Candesartan HCTZ 32/25, IB* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
- 9315G *Blooms the Chemist Candesartan HCTZ 32/25, IB* – **CANDESARTAN + HYDROCHLOROTHIAZIDE**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30
- 8362D *Capecitabine-DRLA, RZ* – **CAPECITABINE**, capecitabine 500 mg tablet, 120
- 13365K *BTC Clopidogrel, JB* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28
- 9354H *BTC Clopidogrel, JB* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28
- 8700X *Blooms the Chemist Escitalopram, IB* – **ESCITALOPRAM**, escitalopram 10 mg tablet, 28
- 8701Y *Blooms the Chemist Escitalopram, IB* – **ESCITALOPRAM**, escitalopram 20 mg tablet, 28
- 13587D *Blooms the Chemist Fenofibrate, IB* – **FENOFIBRATE**, fenofibrate 145 mg tablet, 30
- 9023X *Blooms the Chemist Fenofibrate, IB* – **FENOFIBRATE**, fenofibrate 145 mg tablet, 30
- 1434L *BTC Fluoxetine, JB* – **FLUOXETINE**, fluoxetine 20 mg capsule, 28

13848W	<i>Amaryl, SW</i> – GLIMEPIRIDE , glimepiride 1 mg tablet, 30
8450R	<i>Amaryl, SW</i> – GLIMEPIRIDE , glimepiride 1 mg tablet, 30
8729K	<i>Granisetron Kabi, PK</i> – GRANISETRON , granisetron 3 mg/3 mL injection, 3 mL ampoule
8730L	<i>Granisetron Kabi, PK</i> – GRANISETRON , granisetron 3 mg/3 mL injection, 3 mL ampoule
11784F	<i>Imatinib Sandoz, SZ</i> – IMATINIB , imatinib 100 mg tablet, 60
11787J	<i>Imatinib Sandoz, SZ</i> – IMATINIB , imatinib 100 mg tablet, 60
5443L	<i>Imatinib Sandoz, SZ</i> – IMATINIB , imatinib 100 mg tablet, 60
9111M	<i>Imatinib Sandoz, SZ</i> – IMATINIB , imatinib 100 mg tablet, 60
11778X	<i>Imatinib Sandoz, SZ</i> – IMATINIB , imatinib 400 mg tablet, 30
11788K	<i>Imatinib Sandoz, SZ</i> – IMATINIB , imatinib 400 mg tablet, 30
5444M	<i>Imatinib Sandoz, SZ</i> – IMATINIB , imatinib 400 mg tablet, 30
9112N	<i>Imatinib Sandoz, SZ</i> – IMATINIB , imatinib 400 mg tablet, 30
13435D	<i>Avapro, AV</i> – IRBESARTAN , irbesartan 75 mg tablet, 30
13435D	<i>Blooms the Chemist Irbesartan, IB</i> – IRBESARTAN , irbesartan 75 mg tablet, 30
8246B	<i>Avapro, AV</i> – IRBESARTAN , irbesartan 75 mg tablet, 30
8246B	<i>Blooms the Chemist Irbesartan, IB</i> – IRBESARTAN , irbesartan 75 mg tablet, 30
13380F	<i>Blooms the Chemist Irbesartan, IB</i> – IRBESARTAN , irbesartan 150 mg tablet, 30
8247C	<i>Blooms the Chemist Irbesartan, IB</i> – IRBESARTAN , irbesartan 150 mg tablet, 30
13940Q	<i>Arabloc, AV</i> – LEFLUNOMIDE , leflunomide 10 mg tablet, 30
14068K	<i>Arabloc, AV</i> – LEFLUNOMIDE , leflunomide 10 mg tablet, 30
5449T	<i>Arabloc, AV</i> – LEFLUNOMIDE , leflunomide 10 mg tablet, 30
8374R	<i>Arabloc, AV</i> – LEFLUNOMIDE , leflunomide 10 mg tablet, 30
13411W	<i>BTC Lercanidipine, JB</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
8534E	<i>BTC Lercanidipine, JB</i> – LERCANIDIPINE , lercanidipine hydrochloride 10 mg tablet, 28
13412X	<i>BTC Lercanidipine, JB</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
8679T	<i>BTC Lercanidipine, JB</i> – LERCANIDIPINE , lercanidipine hydrochloride 20 mg tablet, 28
8170B	<i>NOUMED OLANZAPINE, VO</i> – OLANZAPINE , olanzapine 2.5 mg tablet, 28
8185T	<i>NOUMED OLANZAPINE, VO</i> – OLANZAPINE , olanzapine 5 mg tablet, 28
8186W	<i>NOUMED OLANZAPINE, VO</i> – OLANZAPINE , olanzapine 7.5 mg tablet, 28
8187X	<i>NOUMED OLANZAPINE, VO</i> – OLANZAPINE , olanzapine 10 mg tablet, 28
13404L	<i>BTC Perindopril, JB</i> – PERINDOPRIL , perindopril erbumine 2 mg tablet, 30
3050M	<i>BTC Perindopril, JB</i> – PERINDOPRIL , perindopril erbumine 2 mg tablet, 30
13371R	<i>BTC Perindopril, JB</i> – PERINDOPRIL , perindopril erbumine 4 mg tablet, 30
3051N	<i>BTC Perindopril, JB</i> – PERINDOPRIL , perindopril erbumine 4 mg tablet, 30
13372T	<i>BTC Perindopril, JB</i> – PERINDOPRIL , perindopril erbumine 8 mg tablet, 30
8704D	<i>BTC Perindopril, JB</i> – PERINDOPRIL , perindopril erbumine 8 mg tablet, 30
2335X	<i>Blooms The Chemist Pregabalin, IB</i> – PREGABALIN , pregabalin 75 mg capsule, 56
13406N	<i>Blooms the Chemist Rosuvastatin, IB</i> – ROSUVASTATIN , rosuvastatin 5 mg tablet, 30
2606E	<i>Blooms the Chemist Rosuvastatin, IB</i> – ROSUVASTATIN , rosuvastatin 5 mg tablet, 30
13586C	<i>Blooms the Chemist Rosuvastatin, IB</i> – ROSUVASTATIN , rosuvastatin 10 mg tablet, 30
2628H	<i>Blooms the Chemist Rosuvastatin, IB</i> – ROSUVASTATIN , rosuvastatin 10 mg tablet, 30
13588E	<i>Blooms the Chemist Rosuvastatin, IB</i> – ROSUVASTATIN , rosuvastatin 20 mg tablet, 30
2574L	<i>Blooms the Chemist Rosuvastatin, IB</i> – ROSUVASTATIN , rosuvastatin 20 mg tablet, 30
13589F	<i>Blooms the Chemist Rosuvastatin, IB</i> – ROSUVASTATIN , rosuvastatin 40 mg tablet, 30
2594M	<i>Blooms the Chemist Rosuvastatin, IB</i> – ROSUVASTATIN , rosuvastatin 40 mg tablet, 30
8301X	<i>Blooms the Chemist Venlafaxine XR, IB</i> – VENLAFAXINE , venlafaxine 75 mg modified release capsule, 28
8302Y	<i>Blooms the Chemist Venlafaxine XR, IB</i> – VENLAFAXINE , venlafaxine 150 mg modified release capsule, 28

Deletion – Equivalence Indicator

11739W	<i>Solu-Medrol, PF</i> – METHYLPREDNISOLONE , methylprednisolone 40 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber vial
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Deletion – Note

11739W **METHYLPREDNISOLONE**, methylprednisolone 40 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber vial (*Solu-Medrol*)

Alterations

Alteration – Note

12414J **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (*Adalicip, Humira, Yuflyma*)
12454L **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (*Adalicip, Humira, Yuflyma*)
13221W **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (*Adalicip, Yuflyma*)
12330Y **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Abrilada, Amgevita, Hadlima, Hyrimoz, Idacio*)
12356H **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Abrilada, Amgevita, Hadlima, Hyrimoz, Idacio*)
12369B **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Abrilada, Amgevita, Hadlima, Hyrimoz, Idacio*)
12395J **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe (*Humira*)
12408C **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe (*Humira*)
12448E **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device (*Humira*)
12449F **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device (*Humira*)
12450G **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device (*Humira*)
12524E **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe (*Humira*)
11226W **ALECTINIB**, alectinib 150 mg capsule, 4 x 56 (*Alecensa*)
11371L **CABOZANTINIB**, cabozantinib 20 mg tablet, 30 (*Cabometyx*)
11374P **CABOZANTINIB**, cabozantinib 20 mg tablet, 30 (*Cabometyx*)
11368H **CABOZANTINIB**, cabozantinib 40 mg tablet, 30 (*Cabometyx*)
11369J **CABOZANTINIB**, cabozantinib 40 mg tablet, 30 (*Cabometyx*)
11360X **CABOZANTINIB**, cabozantinib 60 mg tablet, 30 (*Cabometyx*)
11367G **CABOZANTINIB**, cabozantinib 60 mg tablet, 30 (*Cabometyx*)
12096P **LORLATINIB**, lorlatinib 25 mg tablet, 90 (*Lorviqua*)
12091J **LORLATINIB**, lorlatinib 100 mg tablet, 30 (*Lorviqua*)
14146M **SECUKINUMAB**, secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (*Cosentyx*)
14154Y **SECUKINUMAB**, secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (*Cosentyx*)
14161H **SECUKINUMAB**, secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (*Cosentyx*)

Alteration – Restriction

12383R **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (*Adalicip, Humira, Yuflyma*)
12414J **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (*Adalicip, Humira, Yuflyma*)
12454L **ADALIMUMAB**, adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices (*Adalicip, Humira, Yuflyma*)
12356H **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Abrilada, Amgevita, Hadlima, Hyrimoz, Idacio*)
12369B **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Abrilada, Amgevita, Hadlima, Hyrimoz, Idacio*)
12385W **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices (*Abrilada, Amgevita, Hadlima, Hyrimoz, Idacio*)
12395J **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe (*Humira*)
12408C **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe (*Humira*)
12448E **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device (*Humira*)
12449F **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device (*Humira*)
12450G **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device (*Humira*)
12524E **ADALIMUMAB**, adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe (*Humira*)
11226W **ALECTINIB**, alectinib 150 mg capsule, 4 x 56 (*Alecensa*)
11976H **BRIGATINIB**, brigatinib 90 mg tablet [7] (&) brigatinib 180 mg tablet [21], 1 pack (*Alunbrig*)
11371L **CABOZANTINIB**, cabozantinib 20 mg tablet, 30 (*Cabometyx*)

11374P	CABOZANTINIB , cabozantinib 20 mg tablet, 30 (<i>Cabometyx</i>)
11368H	CABOZANTINIB , cabozantinib 40 mg tablet, 30 (<i>Cabometyx</i>)
11369J	CABOZANTINIB , cabozantinib 40 mg tablet, 30 (<i>Cabometyx</i>)
11360X	CABOZANTINIB , cabozantinib 60 mg tablet, 30 (<i>Cabometyx</i>)
11367G	CABOZANTINIB , cabozantinib 60 mg tablet, 30 (<i>Cabometyx</i>)
5503P	CARBOMER-980 , carbomer-980 0.2% eye gel, 10 g (<i>Optifresh eye gel, PAA, Viscotears</i>)
8384G	CARBOMER-980 , carbomer-980 0.2% eye gel, 10 g (<i>Optifresh eye gel, PAA, Viscotears</i>)
5507W	CARMELLOSE SODIUM , carmellose sodium 0.5% eye drops, 15 mL (<i>Refresh Tears Plus</i>)
8548X	CARMELLOSE SODIUM , carmellose sodium 0.5% eye drops, 15 mL (<i>Refresh Tears Plus</i>)
9211T	CARMELLOSE SODIUM , carmellose sodium 0.5% eye drops, 15 mL (<i>Refresh Tears Plus</i>)
5508X	CARMELLOSE SODIUM , carmellose sodium 1% eye drops, 15 mL (<i>Refresh Liquigel</i>)
8593G	CARMELLOSE SODIUM , carmellose sodium 1% eye drops, 15 mL (<i>Refresh Liquigel</i>)
9212W	CARMELLOSE SODIUM , carmellose sodium 1% eye drops, 15 mL (<i>Refresh Liquigel</i>)
5556K	CARMELLOSE SODIUM + GLYCEROL , carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL (<i>Optive</i>)
9355J	CARMELLOSE SODIUM + GLYCEROL , carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL (<i>Optive</i>)
9356K	CARMELLOSE SODIUM + GLYCEROL , carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL (<i>Optive</i>)
11056X	CERITINIB , ceritinib 150 mg capsule, 3 x 50 (<i>Zykadia</i>)
10323H	CRIZOTINIB , crizotinib 200 mg capsule, 60 (<i>Xalkori</i>)
11589Y	CRIZOTINIB , crizotinib 200 mg capsule, 60 (<i>Xalkori</i>)
10322G	CRIZOTINIB , crizotinib 250 mg capsule, 60 (<i>Xalkori</i>)
11594F	CRIZOTINIB , crizotinib 250 mg capsule, 60 (<i>Xalkori</i>)
1509K	DEXTRAN-70 + HYPROMELLOSE , dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL (<i>Poly-Tears, Tears Naturale</i>)
5520M	DEXTRAN-70 + HYPROMELLOSE , dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL (<i>Poly-Tears, Tears Naturale</i>)
12092K	ENTRECTINIB , entrectinib 200 mg capsule, 90 (<i>Rozlytrek</i>)
11625W	HYPROMELLOSE , hypromellose 0.3% w/w eye drops, 10 mL (<i>Gentel, In a Wink Moisturising, Revive Tears</i>)
11634H	HYPROMELLOSE , hypromellose 0.3% w/w eye drops, 10 mL (<i>Gentel, In a Wink Moisturising, Revive Tears</i>)
2956N	HYPROMELLOSE , hypromellose 0.5% eye drops, 15 mL (<i>Methopt</i>)
5517J	HYPROMELLOSE , hypromellose 0.5% eye drops, 15 mL (<i>Methopt</i>)
5519L	HYPROMELLOSE + CARBOMER-980 , hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g (<i>Gentel gel, HPMC PAA</i>)
8564R	HYPROMELLOSE + CARBOMER-980 , hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g (<i>Gentel gel, HPMC PAA</i>)
9215B	HYPROMELLOSE + CARBOMER-980 , hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g (<i>Gentel gel, HPMC PAA</i>)
13027P	LAROTRECTINIB , larotrectinib 25 mg capsule, 56 (<i>Vitrakvi</i>)
13043L	LAROTRECTINIB , larotrectinib 100 mg capsule, 56 (<i>Vitrakvi</i>)
13289K	LAROTRECTINIB , larotrectinib 20 mg/mL oral liquid, 2 x 50 mL (<i>Vitrakvi</i>)
12096P	LORLATINIB , lorlatinib 25 mg tablet, 90 (<i>Lorviqua</i>)
12091J	LORLATINIB , lorlatinib 100 mg tablet, 30 (<i>Lorviqua</i>)
5524R	POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL , polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL (<i>Optix, Systane</i>)
8676P	POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL , polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL (<i>Optix, Systane</i>)
14146M	SECUKINUMAB , secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (<i>Cosentyx</i>)
14154Y	SECUKINUMAB , secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (<i>Cosentyx</i>)
14161H	SECUKINUMAB , secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (<i>Cosentyx</i>)
14164L	SECUKINUMAB , secukinumab 150 mg/mL injection, 2 x 1 mL pen devices (<i>Cosentyx</i>)

Alteration – Manufacturer Code

		<i>From</i>	<i>To</i>
2765M	<i>Haldol decanoate</i> – HALOPERIDOL DECANOATE , haloperidol (as decanoate) 50 mg/mL injection, 5 x 1 mL ampoules	JC	IX
2766N	<i>Haldol decanoate</i> – HALOPERIDOL DECANOATE , haloperidol (as decanoate) 150 mg/3 mL injection, 5 x 3 mL ampoules	JC	IX
2622B	<i>Mayne Pharma Oxycodone IR</i> – OXYCODONE , oxycodone hydrochloride 5 mg tablet, 20	YN	SZ
5195K	<i>Mayne Pharma Oxycodone IR</i> – OXYCODONE , oxycodone hydrochloride 5 mg tablet, 20	YN	SZ

Supply Only

When a product is deleted from the Schedule it may be available under Supply Only rules. Supply Only items/brands are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted. Substitution of Supply Only items/brands with products flagged as “equivalent for substitution” still apply as specified in the Schedule at the time the script was written.

Further information on Supply Only arrangements is available at <https://www.pbs.gov.au/browse/medicine-listing/supply-only>

10024N	BUDESONIDE + FORMOTEROL , budesonide 50 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations (<i>Symbicort Rapihaler 50/3</i>)
12100W	BUDESONIDE + FORMOTEROL , budesonide 50 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations (<i>Symbicort Rapihaler 50/3</i>)
9210R	CARBOMER-980 , carbomer-980 0.2% eye gel, 10 g (<i>Optifresh eye gel, PAA, Viscotears</i>)
9249T	COLESTYRAMINE , colestyramine 4 g powder for oral liquid, 50 sachets (<i>Questran Lite</i>)
9216C	DEXTRAN-70 + HYPROMELLOSE , dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL (<i>Poly-Tears, Tears Naturale</i>)
11643T	HYPROMELLOSE , hypromellose 0.3% w/w eye drops, 10 mL (<i>Genteal, In a Wink Moisturising, Revive Tears</i>)
9214Y	HYPROMELLOSE , hypromellose 0.5% eye drops, 15 mL (<i>Methopt</i>)
9217D	PARAFFIN , paraffin 1 g/g eye ointment, 3.5 g (<i>Poly Visc</i>)
9218E	PARAFFIN , paraffin 1 g/g eye ointment, 2 x 3.5 g (<i>Poly Visc, Refresh Night Time</i>)
9219F	POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL , polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL (<i>Optix, Systane</i>)
9308X	TRIGLYCERIDES LONG CHAIN WITH GLUCOSE POLYMER , triglycerides long chain with glucose polymer oral liquid, 18 x 250 mL cartons (<i>ProZero</i>)

Advance Notices**1 October 2024****Deletion – Brand**

10399H	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
10400J	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
10412B	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
10413C	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
10419J	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
10420K	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
10944B	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
10955N	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
10960W	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
10961X	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12325Q	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
12326R	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
12327T	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
12328W	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12329X	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12330Y	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12331B	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
12333D	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
12334E	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12352D	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12353E	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12356H	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12365T	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
12366W	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
12367X	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
12369B	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12370C	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12385W	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12386X	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12387Y	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
12388B	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12401Q	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12402R	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12403T	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12415K	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12416L	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
12420Q	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12434K	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
12437N	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
12438P	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
13686H	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
13692P	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
13721E	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
13722F	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
13744J	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
13754X	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
14222M	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
14243P	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
14251C	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
14261N	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
14262P	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
14263Q	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
14283R	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
14284T	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
5281Y	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
5282B	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
5283C	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
5284D	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
8737W	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
8741C	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
8963R	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
8964T	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
8965W	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
8966X	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
9033K	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
9034L	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
9077R	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
9078T	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
9099X	<i>Idacio, PK – ADALIMUMAB</i> , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9100Y *Idacio, PK – ADALIMUMAB*, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9101B *Idacio, PK – ADALIMUMAB*, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9102C *Idacio, PK – ADALIMUMAB*, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9103D *Idacio, PK – ADALIMUMAB*, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9104E *Idacio, PK – ADALIMUMAB*, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9188N *Idacio, PK – ADALIMUMAB*, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9189P *Idacio, PK – ADALIMUMAB*, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9190Q *Idacio, PK – ADALIMUMAB*, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9191R *Idacio, PK – ADALIMUMAB*, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9425C *Idacio, PK – ADALIMUMAB*, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9426D *Idacio, PK – ADALIMUMAB*, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9427E *Idacio, PK – ADALIMUMAB*, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9428F *Idacio, PK – ADALIMUMAB*, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

11947T *NOUMED AMOXICILLIN, VO – AMOXICILLIN*, amoxicillin 500 mg capsule, 20

1889K *NOUMED AMOXICILLIN, VO – AMOXICILLIN*, amoxicillin 500 mg capsule, 20

3300Q *NOUMED AMOXICILLIN, VO – AMOXICILLIN*, amoxicillin 500 mg capsule, 20

8717T *Tevaripirazole, TB – ARIPIRAZOLE*, aripiprazole 10 mg tablet, 30

8718W *Tevaripirazole, TB – ARIPIRAZOLE*, aripiprazole 15 mg tablet, 30

8719X *Tevaripirazole, TB – ARIPIRAZOLE*, aripiprazole 20 mg tablet, 30

8720Y *Tevaripirazole, TB – ARIPIRAZOLE*, aripiprazole 30 mg tablet, 30

13374X *Atorvastatin GH, GQ – ATORVASTATIN*, atorvastatin 80 mg tablet, 30

8521L *Atorvastatin GH, GQ – ATORVASTATIN*, atorvastatin 80 mg tablet, 30

8200N *Azithromycin Mylan, AF – AZITHROMYCIN*, azithromycin 500 mg tablet, 2

8336R *Azithromycin Mylan, AF – AZITHROMYCIN*, azithromycin 500 mg tablet, 2

11273H *BiResp Spiromax, TB – BUDESONIDE + FORMOTEROL*, budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

11301T *BiResp Spiromax, TB – BUDESONIDE + FORMOTEROL*, budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations

12029D *BiResp Spiromax, TB – BUDESONIDE + FORMOTEROL*, budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

12093L *BiResp Spiromax, TB – BUDESONIDE + FORMOTEROL*, budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

1209P *Cifran, RA – CIPROFLOXACIN*, ciprofloxacin 500 mg tablet, 14

1269T *Pharmacor Cyproterone 50, CR – CYPROTERONE*, cyproterone acetate 50 mg tablet, 20

1270W *Pharmacor Cyproterone 50, CR – CYPROTERONE*, cyproterone acetate 50 mg tablet, 50

13925X *Pharmacor Cyproterone 50, CR – CYPROTERONE*, cyproterone acetate 50 mg tablet, 20

14022B *Pharmacor Cyproterone 100, CR – CYPROTERONE*, cyproterone acetate 100 mg tablet, 50

14023C *Pharmacor Cyproterone 50, CR – CYPROTERONE*, cyproterone acetate 50 mg tablet, 50

8019C *Pharmacor Cyproterone 100, CR – CYPROTERONE*, cyproterone acetate 100 mg tablet, 50

12842X *TE-DASATINIB, AF – DASATINIB*, dasatinib 100 mg tablet, 30

12843Y *TE-DASATINIB, AF – DASATINIB*, dasatinib 50 mg tablet, 60

12849G *TE-DASATINIB, AF – DASATINIB*, dasatinib 20 mg tablet, 60

12850H *TE-DASATINIB, AF – DASATINIB*, dasatinib 20 mg tablet, 60

12857Q *TE-DASATINIB, AF – DASATINIB*, dasatinib 50 mg tablet, 60

12859T *TE-DASATINIB, AF – DASATINIB*, dasatinib 100 mg tablet, 30

12860W *TE-DASATINIB, AF – DASATINIB*, dasatinib 50 mg tablet, 60

12865D *TE-DASATINIB, AF – DASATINIB*, dasatinib 50 mg tablet, 60

12866E *TE-DASATINIB, AF – DASATINIB*, dasatinib 70 mg tablet, 60

12869H *TE-DASATINIB, AF – DASATINIB*, dasatinib 20 mg tablet, 60

12886F *TE-DASATINIB, AF – DASATINIB*, dasatinib 70 mg tablet, 60

12888H *TE-DASATINIB, AF – DASATINIB*, dasatinib 20 mg tablet, 60

12889J	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 100 mg tablet, 30
12890K	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 70 mg tablet, 60
12902C	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 100 mg tablet, 30
12903D	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 70 mg tablet, 60
1354G	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 20 mg tablet, 60
1381Q	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 50 mg tablet, 60
1415L	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 70 mg tablet, 60
1416M	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 100 mg tablet, 30
2478K	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 20 mg tablet, 60
2482P	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 50 mg tablet, 60
2485T	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 70 mg tablet, 60
9125G	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 20 mg tablet, 60
9126H	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 50 mg tablet, 60
9127J	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 70 mg tablet, 60
9342Q	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 100 mg tablet, 30
9343R	<i>TE-DASATINIB, AF</i> – DASATINIB , dasatinib 100 mg tablet, 30
10790X	<i>Dicloxacillin Mylan 500, AL</i> – DICLOXACILLIN , dicloxacillin 500 mg capsule, 24
5097G	<i>Dicloxacillin Mylan 500, AL</i> – DICLOXACILLIN , dicloxacillin 500 mg capsule, 24
8122L	<i>Dicloxacillin Mylan 500, AL</i> – DICLOXACILLIN , dicloxacillin 500 mg capsule, 24
2479L	<i>NOUMED DONEPEZIL, VO</i> – DONEPEZIL , donepezil hydrochloride 10 mg tablet, 28
2532G	<i>NOUMED DONEPEZIL, VO</i> – DONEPEZIL , donepezil hydrochloride 5 mg tablet, 28
8495D	<i>NOUMED DONEPEZIL, VO</i> – DONEPEZIL , donepezil hydrochloride 5 mg tablet, 28
8496E	<i>NOUMED DONEPEZIL, VO</i> – DONEPEZIL , donepezil hydrochloride 10 mg tablet, 28
13401H	<i>Enalapril generichealth, GQ</i> – ENALAPRIL , enalapril maleate 20 mg tablet, 30
1369C	<i>Enalapril generichealth, GQ</i> – ENALAPRIL , enalapril maleate 20 mg tablet, 30
11692J	<i>NOUMED ESOMEPRAZOLE, VO</i> – ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30
12283L	<i>NOUMED ESOMEPRAZOLE, VO</i> – ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30
12287Q	<i>NOUMED ESOMEPRAZOLE, VO</i> – ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30
3401B	<i>NOUMED ESOMEPRAZOLE, VO</i> – ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30
8600P	<i>NOUMED ESOMEPRAZOLE, VO</i> – ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30
8601Q	<i>NOUMED ESOMEPRAZOLE, VO</i> – ESOMEPRAZOLE , esomeprazole 40 mg enteric tablet, 30
8886Q	<i>NOUMED ESOMEPRAZOLE, VO</i> – ESOMEPRAZOLE , esomeprazole 20 mg enteric tablet, 30
13834D	<i>Fluoxetine Capsules 10 mg (Medreich, UK), LM</i> – FLUOXETINE , fluoxetine 10 mg capsule, 30
1834M	<i>Gabapentin generichealth, HQ</i> – GABAPENTIN , gabapentin 300 mg capsule, 100
1835N	<i>Gabapentin generichealth, HQ</i> – GABAPENTIN , gabapentin 400 mg capsule, 100
13402J	<i>Lisinopril generichealth, GQ</i> – LISINOPRIL , lisinopril 20 mg tablet, 30
2458J	<i>Lisinopril generichealth, GQ</i> – LISINOPRIL , lisinopril 20 mg tablet, 30
8561N	<i>Pharmacor Meloxicam 7.5, CR</i> – MELOXICAM , meloxicam 7.5 mg tablet, 30
8562P	<i>Pharmacor Meloxicam 15, CR</i> – MELOXICAM , meloxicam 15 mg tablet, 30
10551H	<i>Rizatriptan ODT GH, GQ</i> – RIZATRIPTAN , rizatriptan 10 mg orally disintegrating tablet, 2
11306C	<i>Tenofovir EMT GH, GQ</i> – TENOFOVIR DISOPROXIL + EMTRICITABINE , tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30
5480K	<i>Valacor 500, CR</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30
8064K	<i>Valacor 500, CR</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 42
8134D	<i>Valacor 500, CR</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30
9288W	<i>Zoledronic Acid SUN, RA</i> – ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 100 mL vial
9350D	<i>Zoledronic Acid SUN, RA</i> – ZOLEDRONIC ACID , zoledronic acid 5 mg/100 mL injection, 100 mL vial

1 November 2024

Deletion – Brand

13896J	<i>Glyade, AF</i> – GLICLAZIDE , gliclazide 80 mg tablet, 100
2449X	<i>Glyade, AF</i> – GLICLAZIDE , gliclazide 80 mg tablet, 100
12785X	<i>Ibavyr, IX</i> – RIBAVIRIN , ribavirin 200 mg tablet, 100
5480K	<i>Valaciclovir generichealth, GQ</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30
8064K	<i>Valaciclovir generichealth, GQ</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 42
8134D	<i>Valaciclovir generichealth, GQ</i> – VALACICLOVIR , valaciclovir 500 mg tablet, 30

Palliative Care

Additions

Addition – Brand

5355W	<i>DIAZEPAM-WGR, WG</i> – DIAZEPAM , diazepam 2 mg tablet, 50
5356X	<i>DIAZEPAM-WGR, WG</i> – DIAZEPAM , diazepam 5 mg tablet, 50
12507G	<i>METOCLOPRAMIDE-WGR, WG</i> – METOCLOPRAMIDE , metoclopramide hydrochloride 10 mg tablet, 25
5372R	<i>OXAZEPAM-WGR, WG</i> – OXAZEPAM , oxazepam 30 mg tablet, 25
5375X	<i>TEMAZEPAM-WGR, WG</i> – TEMAZEPAM , temazepam 10 mg tablet, 25

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Brand

6352H	<i>CICLOSPORIN-WGR, WG</i> – CICLOSPORIN , ciclosporin 25 mg capsule, 30
6353J	<i>CICLOSPORIN-WGR, WG</i> – CICLOSPORIN , ciclosporin 50 mg capsule, 30
6354K	<i>CICLOSPORIN-WGR, WG</i> – CICLOSPORIN , ciclosporin 100 mg capsule, 30

Alterations

Alteration – Restriction

6136Y	GANCICLOVIR , ganciclovir 500 mg injection, 5 vials (<i>Cymevene, GANCICLOVIR SXP</i>)
9675F	VALGANCICLOVIR , valganciclovir 50 mg/mL powder for oral liquid, 100 mL (<i>Valcyte</i>)
6357N	VALGANCICLOVIR , valganciclovir 450 mg tablet, 60 (<i>Valganciclovir Sandoz, Valganciclovir Viatrix</i>)

Advance Notices

1 October 2024

Deletion – Brand

12368Y	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
12384T	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
9679K	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
9680L	<i>Idacio, PK</i> – ADALIMUMAB , adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

1 November 2024

Deletion – Brand

12809E	<i>Ibavyr, IX</i> – RIBAVIRIN , ribavirin 200 mg tablet, 100
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Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Brand

5634M	<i>CICLOSPORIN-WGR, WG</i> – CICLOSPORIN , ciclosporin 25 mg capsule, 30
5635N	<i>CICLOSPORIN-WGR, WG</i> – CICLOSPORIN , ciclosporin 50 mg capsule, 30
5636P	<i>CICLOSPORIN-WGR, WG</i> – CICLOSPORIN , ciclosporin 100 mg capsule, 30

Alterations

Alteration – Restriction

- 5749N **GANCICLOVIR**, ganciclovir 500 mg injection, 5 vials (*Cymevene, GANCICLOVIR SXP*)
9655E **VALGANCICLOVIR**, valganciclovir 50 mg/mL powder for oral liquid, 100 mL (*Valcyte*)
9569P **VALGANCICLOVIR**, valganciclovir 450 mg tablet, 60 (*Valganciclovir Sandoz, Valganciclovir Viatris*)

Advance Notices

1 October 2024

Deletion – Brand

- 12348X *Idacio, PK* – **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
12355G *Idacio, PK* – **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices
9662M *Idacio, PK* – **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes
9663N *Idacio, PK* – **ADALIMUMAB**, adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

1 November 2024

Deletion – Brand

- 12786Y *Ibavyr, IX* – **RIBAVIRIN**, ribavirin 200 mg tablet, 100

Highly Specialised Drugs Program (Community Access)

Additions

Addition – Brand

- 10279B *ENTECAVIR-WGR, WG* – **ENTECAVIR**, entecavir 500 microgram tablet, 30
10353X *ENTECAVIR-WGR, WG* – **ENTECAVIR**, entecavir 1 mg tablet, 30

Advance Notices

1 October 2024

Deletion – Brand

- 10357D *ABACAVIR/LAMIVUDINE 600/300 SUN, RA* – **ABACAVIR + LAMIVUDINE**, abacavir 600 mg + lamivudine 300 mg tablet, 30
10279B *Entecavir Mylan, AF* – **ENTECAVIR**, entecavir 500 microgram tablet, 30
10310P *Viread, GI* – **TENOFOVIR DISOPROXIL**, tenofovir disoproxil fumarate 300 mg tablet, 30
11992E *Viread, GI* – **TENOFOVIR DISOPROXIL**, tenofovir disoproxil fumarate 300 mg tablet, 30
11146P *Tenofovir EMT GH, GQ* – **TENOFOVIR DISOPROXIL + EMTRICITABINE**, tenofovir disoproxil phosphate 291 mg + emtricitabine 200 mg tablet, 30

1 December 2024

Deletion – Brand

- 10304H *Nevirapine Alphapharm, AF* – **NEVIRAPINE**, nevirapine 200 mg tablet, 60

Repatriation Pharmaceutical Benefits

Additions

Addition – Item

- 14567Q **BISACODYL**, bisacodyl 10 mg suppository, 10 (*Dulcolax, Petrus Bisacodyl Suppositories*)
14572Y **BISACODYL**, bisacodyl 10 mg suppository, 12 (*Petrus Bisacodyl Suppositories*)

Deletions

Deletion – Brand

- 10169F *BTC Clopidogrel, JB* – **CLOPIDOGREL**, clopidogrel 75 mg tablet, 28

Advance Notices

1 October 2024

Deletion – Brand

- 4592Q *Gabapentin generichealth, HQ* – **GABAPENTIN**, gabapentin 300 mg capsule, 100
4593R *Gabapentin generichealth, HQ* – **GABAPENTIN**, gabapentin 400 mg capsule, 100

General Pharmaceutical Benefits

■ ACLIDINIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.


Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

aclidinium 322 microgram/actuation inhalation: powder for, 60 actuations

14539F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*110.13	31.60	Bretaris Genuair [FK]

■ ACLIDINIUM + FORMOTEROL

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

Note A LAMA includes tiotropium, glycopyrronium, acclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)


15691

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

aclidinium 340 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

14410K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*152.91	31.60	Brimica Genuair [FK]

■ ADALIMUMAB

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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment.

Treatment criteria:

- Must be treated by a dermatologist.
A maximum of 12 weeks of treatment will be authorised under this restriction.

adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12449F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*1346.05	31.60	Humira [VE]

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12395J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*1346.05	31.60	Humira [VE]

ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing

treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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)

11529

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13221W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1108.87	31.60	^a Adalicip [LR]	^a Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12330Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1108.87	31.60	^a Abirilada [PF] ^a Hadlima [RF] ^a Idacio [PK]	^a Amgevita [XT] ^a Hyrimoz [SZ]

▪ **ADALIMUMAB**

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

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

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment.

Treatment criteria:

- Must be treated by a dermatologist.

A maximum of 12 weeks of treatment will be authorised under this restriction.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12383R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*1108.87	31.60	^a Adalicip [LR] ^a Yuflyma [EW]	^a Humira [VE]

▪ **ADALIMUMAB**

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment.

Treatment criteria:

- Must be treated by a dermatologist.
- A maximum of 12 weeks of treatment will be authorised under this restriction.

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12385W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*1108.87	31.60	^a Abrilada [PF] ^a Hadlima [RF] ^a Idacio [PK]	^a Amgevita [XT] ^a Hyrimoz [SZ]

▪ **ADALIMUMAB**

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note 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

Moderate to severe hidradenitis suppurativa

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

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

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

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

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

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12448E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1346.05	31.60	Humira [VE]

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12408C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1346.05	31.60	Humira [VE]

▪ ADALIMUMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

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

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

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

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
 - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or
 - (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or
 - (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
- Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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)

11718

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient assessed by PCDAI

Clinical criteria:

- Patient must have a documented history of severe Crohn disease, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 40 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR

- Must be treated by a specialist paediatric gastroenterologist.
The measurement of response to the prior course of therapy must be documented in the patient's medical notes.
The PCDAI assessment must be no more than 4 weeks old at the time of application.
Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks providing they continue to sustain the response.

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12436M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*707.17	31.60	^a Amgevita [XT]

adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

14274G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	707.17	31.60	^a Abrilada [PF]

■ ADALIMUMAB

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialed twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

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

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialed.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

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

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

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

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

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

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

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

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

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)

11579

Moderate to severe ulcerative colitis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 while receiving treatment with this drug if aged 6 to 17 years, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be 6 years of age or older.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

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

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12351C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*707.17	31.60	^a Amgevita [XT]

adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes

14253E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	707.17	31.60	^a Abrilada [PF]

ADALIMUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements

any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note 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

Moderate to severe hidradenitis suppurativa

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

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

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

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

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

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

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

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

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

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

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12414J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1108.87	31.60	^a Adalicip [LR] ^a Yuflyma [EW]	^a Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12369B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1108.87	31.60	^a Abrilada [PF] ^a Hadlima [RF] ^a Idacio [PK]	^a Amgevita [XT] ^a Hyrimoz [SZ]

ADALIMUMAB**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note 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

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior to the completion of this course of treatment.

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

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

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

(1) details of the proposed prescription; and

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

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

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

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

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in

biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

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

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
 - (i) the Hurley stage grading; and
 - (ii) the AN count.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.
- Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

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

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

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

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

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
 - (i) the Hurley stage grading; and
 - (ii) the AN count.

adalimumab 80 mg/0.8 mL injection, 0.8 mL pen device

12450G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	*2014.86	31.60	Humira [VE]

adalimumab 80 mg/0.8 mL injection, 0.8 mL syringe

12524E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	*2014.86	31.60	Humira [VE]

■ **ADALIMUMAB**

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Biosimilar prescribing policy

Prescribing of the biosimilar brand Abrilada, Adalicip, Amgevita, Hadlima, Hyrimoz, Idacio, or Yuflyma is encouraged for treatment naive patients.

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

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note 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

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

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

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply

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

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
 - (i) the Hurley stage grading; and
 - (ii) the AN count; and
 - (iii) the name of the antibiotic/s received for two separate courses each of three months; or
 - (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

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

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

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

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

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
 - (i) the Hurley stage grading; and
 - (ii) the AN count.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.
- Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

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

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

At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply.

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

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
 - (i) the Hurley stage grading; and
 - (ii) the AN count.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12454L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	*1659.06	31.60	^a Adalicip [LR] ^a Yuflyma [EW]	^a Humira [VE]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12356H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	*1659.06	31.60	^a Abrilada [PF] ^a Hadlima [RF] ^a Idacio [PK]	^a Amgevita [XT] ^a Hyrimoz [SZ]

▪ ALECTINIB

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

alectinib 150 mg capsule, 4 x 56

11226W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6483.03	31.60	Alecensa [RO]

▪ AMANTADINE**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.

Restricted benefit

Parkinson disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be drug induced.

amantadine hydrochloride 100 mg capsule, 100

14486K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*55.67	31.60	^a AMANTAMED [DZ]	^a Symmetrel 100 [NV]

▪ **AMOXICILLIN + CLAVULANIC ACID**

Caution Hepatotoxicity has been reported with this drug.

Note Pharmaceutical benefits that have the brand CLAVULIN-125F (GlaxoSmithKline, Canada) may be substituted for pharmaceutical benefits that have the brand Curam in the case of a shortage.

Restricted benefit

Infection where resistance to amoxicillin is suspected

Restricted benefit

Infections where resistance to amoxicillin is proven

amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL

5009P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	#19.53	21.40	^a Curam [SZ]

amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 100 mL

14568R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
DP	‡1	61.76	31.60	^a CLAVULIN-125F (GlaxoSmithKline, Canada) [DZ]

▪ **AMOXICILLIN + CLAVULANIC ACID**

Caution Hepatotoxicity has been reported with this drug.

Note Pharmaceutical benefits that have the brand CLAVULIN-125F (GlaxoSmithKline, Canada) may be substituted for pharmaceutical benefits that have the brand Curam in the case of a shortage.

Restricted benefit

Infection where resistance to amoxicillin is suspected

Restricted benefit

Infections where resistance to amoxicillin is proven

amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 75 mL

1892N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	#19.53	21.40	^a Curam [SZ]

amoxicillin 125 mg/5 mL + clavulanic acid 31.25 mg/5 mL powder for oral liquid, 100 mL

14569T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	1	..	61.76	31.60	^a CLAVULIN-125F (GlaxoSmithKline, Canada) [DZ]

▪ **APOMORPHINE**

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15542

Parkinson disease

Treatment Phase: Maintenance therapy

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules

14407G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	72	5	..	*12222.03	31.60	Movapo [TD]

apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials

14375N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	36	5	..	*15017.07	31.60	Apomine Solution for Infusion [IT]

apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes

14377Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	72	5	..	*16197.15	31.60	Movapo PFS [TD]

■ APOMORPHINE

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

Note Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Note Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

Authority required (STREAMLINED)**15542**

Parkinson disease

Treatment Phase: Maintenance therapy

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- Patient must have been commenced on treatment in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices

14485J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	40	5	..	*5338.27	31.60	^a Movapo Pen [TD]

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges

14309D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	40	5	..	*5338.27	31.60	^a Apomine Intermittent [IT]

■ ATEZOLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**10917**

Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma

Treatment Phase: Continuing treatment of hepatocellular carcinoma - 3 weekly treatment regimen

Treatment criteria:

- Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition. PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time

atezolizumab 1.875 g/15 mL injection, 15 mL vial

14566P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	8	..	6909.97	31.60	Tecentriq SC [RO]

■ AZITHROMYCIN

Note Pharmaceutical benefits that have the brand Azithromycin (Zydus, USA) may be substituted for pharmaceutical benefits that have the brand Zithromax in the case of a shortage.

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

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

Restricted benefit

Trachoma

azithromycin 200 mg/5 mL powder for oral liquid, 15 mL

14570W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	#61.20	31.60	^a Azithromycin (Zydus, USA) [DZ]

azithromycin 200 mg/5 mL powder for oral liquid, 15 mL

8201P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	#29.06	30.93	^a Zithromax [PF]

■ BECLOMETASONE**Restricted benefit**

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be unable to achieve co-ordinated use of other metered dose inhalers containing this drug.

beclometasone dipropionate 100 microgram/actuation breath activated inhalation, 200 actuations

14514X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡2	5	..	*49.41	31.60	Qvar 100 Autohaler [IL]

beclometasone dipropionate 50 microgram/actuation breath activated inhalation, 200 actuations

14378R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡2	5	..	*37.03	31.60	Qvar 50 Autohaler [IL]

■ BECLOMETASONE**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

beclometasone dipropionate 50 microgram/actuation inhalation, 200 actuations

14540G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡2	5	..	*27.61	29.06	Qvar 50 [IL]

beclometasone dipropionate 100 microgram/actuation inhalation, 200 actuations

14541H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡2	5	..	*43.19	31.60	Qvar 100 [IL]

■ BECLOMETASONE + FORMOTEROL

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Note This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

Authority required (STREAMLINED)**15599**

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; 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 and require single maintenance and reliever therapy.

Population criteria:

- Patient must be at least 18 years of age.

beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations

14376P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡2	5	..	*61.49	31.60	Fostair [EU]

■ BECLOMETASONE + FORMOTEROL

Note This product is not indicated for the initiation of treatment in asthma

Note This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Note This product is not PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This product is not PBS-subsidised for use as 'anti-inflammatory reliever' therapy for mild asthma.

Authority required (STREAMLINED)

15656

Asthma


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 18 years or older.

beclometasone dipropionate 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations

14538E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*82.55	31.60	Fostair 200/6 [EU]

▪ **BECLOMETASONE + FORMOTEROL + GLYCOPYRRONIUM**

Note Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at <http://copdx.org.au/>); the assessment and adherence to correct technique should be documented in the patient's medical records.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

15543

Chronic obstructive pulmonary disease (COPD)


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

Treatment criteria:

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

beclometasone dipropionate 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation + glycopyrronium 10 microgram/actuation inhalation, 120 actuations

14310E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*151.87	31.60	Trimbow [EU]


▪ **BETAXOLOL**

Note For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

betaxolol 0.5% eye drops, 5 mL

14425F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*27.99	29.44	^a BetoQuin [NM]
			^b 9.52	*37.51	29.44	^a Betoptic [NV]

▪ **BIMATOPROST**

Note For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

bimatoprost 0.03% eye drops, 3 mL

14315K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±2	5	..	*52.93	31.60	^a Bimatoprost Sandoz [SZ] ^a Bimprozt [TY] ^a Lumigan [VE]	^a BIMATOPROST-WGR [WG] ^a Bimtop [AF]

bimatoprost 0.03% eye drops, 30 x 0.4 mL ampoules

14422C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*46.61	31.60	Lumigan PF [VE]

■ BIMATOPROST + TIMOLOL

Note For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

bimatoprost 0.03% + timolol 0.5% eye drops, 3 mL

14317M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*60.65	31.60	Ganfort 0.3/5 [VE]

bimatoprost 0.03% + timolol 0.5% eye drops, 30 x 0.4 mL ampoules

14351H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*56.11	31.60	GANfort PF 0.3/5 [VE]

■ BISACODYL**Restricted benefit**

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

Restricted benefit

Terminal malignant neoplasia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Anorectal congenital abnormalities

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.


Restricted benefit

Megacolon

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

bisacodyl 5 mg enteric tablet, 200

14446H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*22.07	23.52	Lax-Tab [AE]

▪ **BISACODYL**

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Terminal malignant neoplasia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Anorectal congenital abnormalities

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

Restricted benefit

Megacolon


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Population criteria:

- Patient must identify as Aboriginal or Torres Strait Islander.

bisacodyl 10 mg suppository, 10

14447J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*38.73	31.60	^a Petrus Bisacodyl Suppositories [PP]
			^B 2.58	*41.31	31.60	^a Dulcolax [VZ]

bisacodyl 10 mg suppository, 12

14305X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	6	4	..	*36.03	31.60	Petrus Bisacodyl Suppositories [PP]

■ BRIGATINIB

Caution Careful monitoring of patients is required due to risk of developing pulmonary adverse events observed in patients within the first seven days of treatment with this drug. Patients must be instructed to report any new or worsening respiratory symptoms.

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

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

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

brigatinib 90 mg tablet [7] (&) brigatinib 180 mg tablet [21], 1 pack

11976H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±1	6815.68	31.60	Alunbrig [TK]

■ BRIMONIDINE

Note For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

brimonidine tartrate 0.15% eye drops, 5 mL

14496Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*28.87	30.32	Alphagan P 1.5 [VE]

brimonidine tartrate 0.2% eye drops, 5 mL

14497B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*29.81	31.26	^a Enidin [VB]
			^b 1.96	*31.77	31.26	^a Alphagan [VE]

■ BRIMONIDINE + TIMOLOL

Note For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brimonidine tartrate 0.2% + timolol 0.5% eye drops, 5 mL

14491Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*38.91	31.60	Combigan [VE]

■ BRINZOLAMIDE

Note For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

brinzolamide 1% eye drops, 5 mL

14321R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*32.95	31.60	^a BrinzoQuin [NM]
			^b 6.54	*39.49	31.60	^a Azopt [NV]

▪ BRINZOLAMIDE + BRIMONIDINE

Note For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brinzolamide 1% + brimonidine tartrate 0.2% eye drops, 5 mL

14423D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*36.15	31.60	Simbrinza 1%/0.2% [NV]

▪ BRINZOLAMIDE + TIMOLOL

Note For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

brinzolamide 1% + timolol 0.5% eye drops, 5 mL

14495X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*39.89	31.60	Azarga [NV]

▪ BUDESONIDE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

budesonide 100 microgram/actuation powder for inhalation, 200 actuations

14331G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*32.07	31.60	Pulmicort Turbuhaler [AP]

budesonide 200 microgram/actuation powder for inhalation, 200 actuations

14503H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*46.83	31.60	Pulmicort Turbuhaler [AP]

budesonide 400 microgram/actuation powder for inhalation, 200 actuations

14470N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*57.61	31.60	Pulmicort Turbuhaler [AP]

▪ BUDESONIDE

Authority required (STREAMLINED)

15578

Severe chronic asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must require long-term steroid therapy, **AND**
- Patient must not be able to use other forms of inhaled steroid therapy.

budesonide 1 mg/2 mL inhalation solution, 30 x 2 mL ampoules

14469M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*61.59	31.60	Pulmicort Respules [AP]

budesonide 500 microgram/2 mL inhalation solution, 30 x 2 mL ampoules

14438X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*56.77	31.60	Pulmicort Respules [AP]

▪ BUDESONIDE

Note Continuing Therapy Only:

For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a

patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Authority required (STREAMLINED)

15772


Mild to moderate Crohn disease

Clinical criteria:

- The condition must affect the ileum; OR
- The condition must affect the ascending colon; OR
- The condition must affect the ileum and ascending colon.

The total duration of therapy should be no more than 10 weeks in any single course.

budesonide 3 mg enteric capsule, 50

14571X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*67.61	31.60	Budenofalk [FD]

▪ **BUDESONIDE + FORMOTEROL**

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15577

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have failed PBS-subsidised fluticasone propionate and salmeterol as a fixed dose combination for this condition.

Treatment criteria:

- Must be treated by a respiratory physician; OR
- Must be treated by a paediatrician.

budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

14437W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*68.49	31.60	Symbicort Turbuhaler 100/6 [AP]

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

14365C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±2	5	..	*61.49	31.60	^a BiResp Spiromax [TB]	^a DuoResp Spiromax [EV]
						^a Rilast TURBUHALER 200/6 [XT]	
			^B 8.00	*69.49	31.60	^a Symbicort Turbuhaler 200/6 [AP]	

budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations

14535B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±4	5	..	*71.11	31.60	^a Rilast RAPIHALER 100/3 [XT]
			^B 9.92	*81.03	31.60	^a Symbicort Rapihaler 100/3 [AP]

▪ **BUDESONIDE + FORMOTEROL**

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15755

Asthma

Clinical criteria:


- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; 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 and require single maintenance and reliever therapy.

Population criteria:

- Patient must be aged 12 years or over.

budesonide 100 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

14440B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*68.49	31.60	Symbicort Turbuhaler 100/6 [AP]

■ BUDESONIDE + FORMOTEROL

Note Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15577

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have failed PBS-subsidised fluticasone propionate and salmeterol as a fixed dose combination for this condition.

Treatment criteria:

- Must be treated by a respiratory physician; OR
- Must be treated by a paediatrician.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations

14436T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±4	5	..	*108.35	31.60	^a Rilast RAPIHALER 200/6 [XT]
			^b 10.16	*118.51	31.60	^a Symbicort Rapihaler 200/6 [AP]

■ BUDESONIDE + FORMOTEROL

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15702

Asthma


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; 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.

Population criteria:

- Patient must be aged 12 years or over.

budesonide 100 microgram/actuation + formoterol fumarate dihydrate 3 microgram/actuation inhalation, 120 actuations

14467K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*71.11	31.60	^a Rilast RAPIHALER 100/3 [XT]
			^b 9.92	*81.03	31.60	^a Symbicort Rapihaler 100/3 [AP]

▪ **BUDESONIDE + FORMOTEROL**

Note Pharmaceutical benefits that have the brand BiResp Spiromax 200/6 powder for inhalation, 120 actuations, DuoResp Spiromax 200/6 powder for inhalation, 120 actuations, Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

Note Patient must be aged 18 years or older.

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)


15680

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; 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 and require single maintenance and reliever therapy.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

14434Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±2	5	..	*61.49	31.60	^a BiResp Spiromax [TB]	^a DuoResp Spiromax [EV]

▪ **BUDESONIDE + FORMOTEROL**

Note Pharmaceutical benefits that have the brand BiResp Spiromax 200/6 powder for inhalation, 120 actuations, DuoResp Spiromax 200/6 powder for inhalation, 120 actuations, Symbicort Turbuhaler 200/6 powder for inhalation, 120 actuations and Rilast TURBUHALER 200/6 powder for inhalation, 120 actuations are equivalent for the purposes of substitution.

Note Patient must be aged 12 years or over.

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)


15680

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; 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 and require single maintenance and reliever therapy.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 120 actuations

14439Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*61.49	31.60	^a Rilast TURBUHALER 200/6 [XT]
			^B 8.00	*69.49	31.60	^a Symbicort Turbuhaler 200/6 [AP]

▪ **BUDESONIDE + FORMOTEROL**

Authority required (STREAMLINED)

15615

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

Note Unlike Symbicort Turbuhaler 200/6, Symbicort Rapihaler 200/6 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy as the approved Product Information does not specify such use.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15548

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

budesonide 200 microgram/actuation + formoterol fumarate dihydrate 6 microgram/actuation inhalation, 120 actuations

14468L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	5	..	*108.35	31.60	^a Rilast RAPIHALER 200/6 [XT]
			^B 10.16	*118.51	31.60	^a Symbicort Rapihaler 200/6 [AP]

■ BUDESONIDE + FORMOTEROL

Note For prescriptions written for the Maximum Quantity of 2 inhalers (units), item code 11301T (2x60 pack) and item code 13258T (1x60 pack) are substitutable when dispensing 2 inhalers.

Note Pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations and pharmaceutical benefits that have the form budesonide 400 microgram/actuation + formoterol (eformoterol) fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations are equivalent for the purposes of substitution when dispensing 2 inhalers at one time.

Authority required (STREAMLINED)

15617

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Note Patient must be aged 18 years or older.

Note Budesonide/formoterol fumarate dihydrate powder for inhalation 400/12 microgram strength inhalers are not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15548

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

14398T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	..	*108.39	31.60	^a Bufomix Easyhaler 400/12 [OX]	^a DuoResp Spiromax [EV]
						^a Rilast TURBUHALER 400/12 [XT]	
			^B 8.12	*116.51	31.60	^a Symbicort TURBUHALER 400/12 [AP]	

budesonide 400 microgram/actuation + formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 2 x 60 actuations

14435R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*108.39	31.60	^a BiResp Spiromax [TB]	^a DuoResp Spiromax [EV]

■ BUDESONIDE + GLYCOPYRRONIUM + FORMOTEROL

Note Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at <http://copdx.org.au/>); the assessment and adherence to correct technique should be documented in the patient's medical records.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

15543

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

Treatment criteria:

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

budesonide 160 microgram/actuation + glycopyrronium 7.2 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations

14536C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*146.03	31.60	Breztri Aerosphere [AP]

■ CABERGOLINE

Caution Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

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.

Restricted benefit

Parkinson disease


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

cabergoline 1 mg tablet, 30

14516B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*86.41	31.60	Cabaser [PF]

cabergoline 2 mg tablet, 30

14543K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*111.23	31.60	Cabaser [PF]

▀ CABOZANTINIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

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

Note Special Pricing Arrangements apply.

Note A prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: <https://www.mdcalc.com/imdc-international-metastatic-renal-cell-carcinoma>.

One point is assigned for each of:

(i) a time of diagnosis to systemic therapy of less than 1 year

(ii) a Karnofsky Performance Status of less than 80%

(iii) a haemoglobin less than the lower limit of normal

(iv) a corrected calcium level greater than the upper limit of normal

(v) a neutrophil count greater than the upper limit of normal

(vi) a platelet count greater than the upper limit of normal

Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.

Favourable IMDC risk is a score of 0.

Intermediate IMDC risk is a score of 1 to 2.

Poor IMDC risk is a score of 3 to 6.

Document any IMDC risk score assessment in the patient's medical records.

Authority required (STREAMLINED)**15774**

Stage IV renal cell carcinoma (RCC)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be each of: (i) classified as having an intermediate to poor survival risk score according to the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC), (ii) untreated with a tyrosine kinase inhibitor; OR
- Patient must have progressive disease according to the Response Evaluation Criteria in Solid Tumours (RECIST) despite treatment with a tyrosine kinase inhibitor, irrespective of the current IMDC survival risk score, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Patient must be undergoing treatment with this drug for the first time at the time of the first PBS prescription.

cabozantinib 20 mg tablet, 30

11371L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9472.60	31.60	Cabometyx [IS]

cabozantinib 40 mg tablet, 30

11369J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9472.60	31.60	Cabometyx [IS]

cabozantinib 60 mg tablet, 30

11360X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	9472.60	31.60	Cabometyx [IS]

▀ CABOZANTINIB

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:

Complete response (CR) is disappearance of all target lesions.

Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.

Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.

Stable disease (SD) is small changes that do not meet above criteria.

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**15775**

Stage IV renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Authority required (STREAMLINED)

15757

Stage IV renal cell carcinoma (RCC)

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

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 September 2024, **AND**
- Patient must have had a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records if not already documented, **AND**
- Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Note A prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: <https://www.mdcalc.com/imdc-international-metastatic-renal-cell-carcinoma>.

One point is assigned for each of:

- (i) a time of diagnosis to systemic therapy of less than 1 year
- (ii) a Karnofsky Performance Status of less than 80%
- (iii) a haemoglobin less than the lower limit of normal
- (iv) a corrected calcium level greater than the upper limit of normal
- (v) a neutrophil count greater than the upper limit of normal
- (vi) a platelet count greater than the upper limit of normal

Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.

Favourable IMDC risk is a score of 0.

Intermediate IMDC risk is a score of 1 to 2.

Poor IMDC risk is a score of 3 to 6.

Document any IMDC risk score assessment in the patient's medical records.

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

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

cabozantinib 20 mg tablet, 30

11374P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9472.60	31.60	Cabometyx [IS]

cabozantinib 40 mg tablet, 30

11368H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9472.60	31.60	Cabometyx [IS]

cabozantinib 60 mg tablet, 30

11367G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	9472.60	31.60	Cabometyx [IS]

■ **CARBAMAZEPINE**

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.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

carbamazepine 100 mg tablet, 100

14509P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	2	..	*34.31	31.60	^a Carbamazepine Sandoz [NM]
			^b 5.32	*39.63	31.60	^a Tegretol 100 [NV]

carbamazepine 200 mg tablet, 100

14338P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	2	..	*48.31	31.60	^a Carbamazepine Sandoz [NM]
			^b 5.24	*53.55	31.60	^a Tegretol 200 [NV]

▪ **CARBOMER-980**

Restricted benefit

Severe dry eye syndrome

carbomer-980 0.2% eye gel, 10 g

5503P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±1	5	..	16.81	18.26	^a Optifresh eye gel [PP]	^a PAA [UL]
			^B 3.85	20.66	18.26	^a Viscotears [UO]	

carbomer-980 0.2% eye gel, 10 g

8384G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	16.81	18.26	^a Optifresh eye gel [PP]	^a PAA [UL]
			^B 3.85	20.66	18.26	^a Viscotears [UO]	

▪ **CARBOMER-980**

Restricted benefit

Severe dry eye syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

carbomer-980 0.2% eye gel, 10 g

14385D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP NP	±2	5	..	*20.17	21.62	^a Optifresh eye gel [PP]	^a PAA [UL]
			^B 7.70	*27.87	21.62	^a Viscotears [UO]	

▪ **CARBOMER-980**

Authority required (STREAMLINED)

15559

Severe dry eye syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

carbomer-980 0.2% eye drops, 30 x 600 mg ampoules

14420Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	6	5	..	*48.81	31.60	Viscotears Gel PF [UO]

▪ **CARMELLOSE SODIUM**

Restricted benefit

Severe dry eye syndrome

carmellose sodium 1% eye drops, 15 mL

5508X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	16.61	18.06	Refresh Liquigel [VE]

carmellose sodium 1% eye drops, 15 mL

8593G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	16.61	18.06	Refresh Liquigel [VE]

carmellose sodium 0.5% eye drops, 15 mL

5507W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	16.61	18.06	Refresh Tears Plus [VE]

carmellose sodium 0.5% eye drops, 15 mL

8548X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	16.61	18.06	Refresh Tears Plus [VE]

▪ **CARMELLOSE SODIUM**

Authority required (STREAMLINED)


15559

Severe dry eye syndrome


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

carmellose sodium 1% eye drops, 30 x 0.4 mL ampoules

14452P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*40.83	31.60	Celluvisc [VE]

carmellose sodium 0.5% eye drops, 30 x 0.4 mL ampoules

14522H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*40.83	31.60	Cellufresh [VE]

■ CARMELLOSE SODIUM

Note The in-use shelf life of Evolve carmellose 0.5% and Evolve hypromellose 0.3% is 3 months from the date of opening.


Authority required (STREAMLINED)**15559**

Severe dry eye syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

carmellose sodium 0.5% eye drops, 10 mL

14319P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡2	5	..	*36.57	31.60	Evolve Carmellose [CX]

■ CARMELLOSE SODIUM

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

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

Restricted benefit

Severe dry eye syndrome

Clinical criteria:

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

carmellose sodium 1% eye drops, 15 mL

9212W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	16.61	18.06	Refresh Liquigel [VE]


carmellose sodium 0.5% eye drops, 15 mL

9211T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	11	..	16.61	18.06	Refresh Tears Plus [VE]


■ CARMELLOSE SODIUM + GLYCEROL**Restricted benefit**

Severe dry eye syndrome

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

5556K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	16.61	18.06	Optive [VE]

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

9355J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	3	..	16.61	18.06	Optive [VE]

■ CARMELLOSE SODIUM + GLYCEROL

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

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

Restricted benefit

Severe dry eye syndrome

Clinical criteria:

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

carmellose sodium 0.5% + glycerol 0.9% eye drops, 15 mL

9356K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	7	..	16.61	18.06	Optive [VE]

■ CERITINIB

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

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

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

ceritinib 150 mg capsule, 3 x 50


11056X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6934.49	31.60	Zykadia [NV]

▪ **CICLESONIDE**


Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

ciclesonide 160 microgram/actuation inhalation, 120 actuations

14348E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*53.03	31.60	Alvesco 160 [EU]

ciclesonide 80 microgram/actuation inhalation, 120 actuations

14312G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*35.15	31.60	Alvesco 80 [EU]

▪ **CITALOPRAM**

Restricted benefit

Major depressive disorders


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.


citalopram 10 mg tablet, 28

14313H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*18.89	20.34	^a Celapram [AF]	^a Talam [RW]

citalopram 20 mg tablet, 28

14490P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*18.89	20.34	^a APO-Citalopram [TX] ^a Celapram [AF] ^a NOUMED CITALOPRAM [VO]	^a APX-Citalopram [TY] ^a Citalopram Sandoz [SZ] ^a Talam [RW]
			^B 26.30	*45.19	20.34	^a Cipramil [LU]	

citalopram 40 mg tablet, 28

14518D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*18.97	20.42	^a APO-Citalopram [TX] ^a Citalopram Sandoz [SZ] ^a Talam [RW]	^a Celapram [AF] ^a NOUMED CITALOPRAM [VO]

▪ **CITRIC ACID + LAURYL SULFOACETATE SODIUM + SORBITOL**

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic or quadriplegic or have severe neurogenic impairment of bowel function.

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care on account of age, infirmity or other condition in a hospital, nursing home or residential facility.

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving long-term nursing care and in respect of whom a Carer Allowance is payable as a disabled adult.

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

Restricted benefit

Terminal malignant neoplasia

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Anorectal congenital abnormalities

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.


Restricted benefit

Megacolon

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

sodium citrate dihydrate 450 mg/5 mL + lauryl sulfoacetate sodium 45 mg/5 mL + sorbitol 3.125 g/5 mL enema, 12 x 5 mL


14534Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*60.95	31.60	Micolette [AE]

▪ **COLESTYRAMINE**

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

colestyramine 4 g powder for oral liquid, 50 sachets

14477Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*154.23	31.60	Questran Lite [GO]

▪ **CRIZOTINIB**

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

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

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

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

The following must be documented in the patient's medical records:

(a) evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

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

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

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

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

crizotinib 200 mg capsule, 60

10323H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6934.49	31.60	Xalkori [PF]

crizotinib 250 mg capsule, 60

10322G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6934.49	31.60	Xalkori [PF]

▪ **CRIZOTINIB**

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing, **AND**
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal.

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

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

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

The following must be documented in the patient's medical records:

(a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

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

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

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

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

crizotinib 200 mg capsule, 60

11589Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6934.49	31.60	Xalkori [PF]

crizotinib 250 mg capsule, 60

11594F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	6934.49	31.60	Xalkori [PF]

▪ **DESVENLAFAXINE**

Note Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 50 mg, desvenlafaxine tablet (modified release) 50 mg (as benzoate) and desvenlafaxine tablet (extended release) 50 mg (as succinate) are equivalent for the purposes of substitution.

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.


Restricted benefit

Major depressive disorders


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.


desvenlafaxine 50 mg modified release tablet, 28

14383B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*29.97	31.42	^a BTC Desvenlafaxine [BG] ^a DESVEN [RW] ^a DESVENLAFAXINE-WGR XR [WG]	^a Desfax [AF] ^a Desvenlafaxine Sandoz [SZ]

desvenlafaxine 50 mg modified release tablet, 28

14418W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*29.97	31.42	^a APO-Desvenlafaxine MR [TX]	^a Desvenlafaxine GH XR [GQ]

desvenlafaxine 50 mg modified release tablet, 28

14451N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*29.97	31.42	^a Pristiq [PF]

▪ **DESVENLAFAXINE**

Note Pharmaceutical benefits that have the forms desvenlafaxine tablet (modified release) 100 mg, desvenlafaxine tablet (modified release) 100 mg (as benzoate) and desvenlafaxine tablet (extended release) 100 mg (as succinate) are equivalent for the purposes of substitution.

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.

Restricted benefit

Major depressive disorders

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

desvenlafaxine 100 mg modified release tablet, 28

14384C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*33.73	31.60	^a APO-Desvenlafaxine MR [TX]	^a Desvenlafaxine GH XR [GQ]

desvenlafaxine 100 mg modified release tablet, 28

14489N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*33.73	31.60	^a BTC Desvenlafaxine [BG]	^a Desfax [AF]
						^a DESVEN [RW]	^a Desvenlafaxine Sandoz [SZ]
						^a DESVENLAFAXINE-WGR XR [WG]	

desvenlafaxine 100 mg modified release tablet, 28

14545M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*33.73	31.60	^a Pristiq [PF]	

▪ DEXTRAN-70 + HYPROMELLOSE**Restricted benefit**

Severe dry eye syndrome

dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

1509K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	‡1	5	..	17.22	18.67	^a Poly-Tears [IQ]	
			^B 4.00	21.22	18.67	^a Tears Naturale [AQ]	

dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

5520M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	‡1	5	..	17.22	18.67	^a Poly-Tears [IQ]	
			^B 4.00	21.22	18.67	^a Tears Naturale [AQ]	

▪ DEXTRAN-70 + HYPROMELLOSE**Restricted benefit**

Severe dry eye syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

dextran-70 0.1% + hypromellose 0.3% eye drops, 15 mL

14521G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP NP	‡2	5	..	*20.99	22.44	^a Poly-Tears [IQ]	
			^B 8.00	*28.99	22.44	^a Tears Naturale [AQ]	

▪ DILTIAZEM**Caution** The myocardial depressant effects of this drug and of beta-blocking drugs are additive.**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

diltiazem hydrochloride 180 mg modified release capsule, 30

14564M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*26.91	28.36	^a Diltiazem Sandoz CD [SZ]	^a Vasocardol CD [AV]
			^B 3.80	*30.71	28.36	^a Cardizem CD [SW]	

diltiazem hydrochloride 240 mg modified release capsule, 30

14508N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*31.65	31.60	^a Diltiazem Sandoz CD [SZ]	^a Vasocardol CD [AV]
			^B 3.80	*35.45	31.60	^a Cardizem CD [SW]	

diltiazem hydrochloride 360 mg modified release capsule, 30

14565N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*37.29	31.60	^a Diltiazem Sandoz CD [SZ]	^a Vasocardol CD [AV]
			^B 3.80	*41.09	31.60	^a Cardizem CD [SW]	

diltiazem hydrochloride 60 mg tablet, 90

14479C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*29.39	30.84	^a Vasocardol [AV]	
			^B 3.80	*33.19	30.84	^a Cardizem [SW]	

▪ DORZOLAMIDE**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

dorzolamide 2% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
14524K	±2	5	..	*24.07	25.52	^a Trusamide [AF]	^a Trusopt [MF]

OP

▪ DORZOLAMIDE + TIMOLOL

Note For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

dorzolamide 2% + timolol 0.5% eye drops, 5 mL

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
14386E	±2	5	..	*30.53	31.60	^a Cosdor [AF]	^a Vizo-PF Dorzolotim [AE]
			^B 1.60	*32.13	31.60	^a Cosopt [MF]	

OP

▪ DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 100 mg (as hyclate (hydrochloride)), doxycycline tablet 100 mg (as monohydrate) and doxycycline modified release capsule 100 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

Restricted benefit

Severe acne

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

doxycycline 100 mg modified release capsule, 7

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14443E	8	2	^B 12.32	*47.31	31.60	^a Mayne Pharma Doxycycline [YT]
			^B 23.60	*58.59	31.60	^a Doryx [YN]

doxycycline 100 mg tablet, 7

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
14480D	8	2	..	*34.99	31.60	^a APX-Doxycycline [TX]	^a Doxsig [RW]
						^a DOXYCYCLINE-WGR [WG]	^a Doxylin 100 [AF]

doxycycline 100 mg tablet, 7

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14511R	8	2	..	*34.99	31.60	^a Doxycycline Sandoz [HX]

▪ DOXYCYCLINE

Note Pharmaceutical benefits that have the forms doxycycline tablet 50 mg (as hyclate (hydrochloride)), doxycycline tablet 50 mg (as monohydrate) and doxycycline modified release capsule 50 mg (as hyclate (hydrochloride)) are equivalent for the purposes of substitution.

Restricted benefit

Bronchiectasis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Population criteria:

- Patient must be aged 8 years or older.

Restricted benefit

Chronic bronchitis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Population criteria:

- Patient must be aged 8 years or older.

Restricted benefit

Severe acne

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

doxycycline 50 mg modified release capsule, 25

14484H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	^B 5.16	*24.39	20.68	^a Mayne Pharma Doxycycline [YT]
			^B 10.00	*29.23	20.68	^a Doryx [YN]

doxycycline 50 mg tablet, 25

14307B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*19.23	20.68	^a APX-Doxycycline [TX]	^a Doxsig [RW]
						^a DOXYCYCLINE-WGR [WG]	^a Doxylin 50 [AF]

doxycycline 50 mg tablet, 25

14513W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*19.23	20.68	^a Doxycycline Sandoz [HX]

ENTACAPONE**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.

Restricted benefit

Parkinson disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

entacapone 200 mg tablet, 100

14542J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	4	4	..	*349.99	31.60	Comtan [SZ]

ENTRECTINIB

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing, **AND**
- Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR
- Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal.

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

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

- details of the proposed prescription; and
- a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be documented in the patient's medical records:

- evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

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

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

entrectinib 200 mg capsule, 90

12092K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7290.90	31.60	Rozlytrek [RO]

▪ **EPROSARTAN + HYDROCHLOROTHIAZIDE**


Restricted benefit

Hypertension

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must not be for the initiation of anti-hypertensive therapy, **AND**
- The condition must be inadequately controlled with an angiotensin II antagonist; OR
- The condition must be inadequately controlled with a thiazide diuretic.

eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28

14337N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*39.05	31.60	Teveten Plus 600/12.5 [GO]

▪ **ERYTHROMYCIN**

Authority required (STREAMLINED)

15710

Severe acne

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be one in which tetracycline therapy is inappropriate.

erythromycin 250 mg enteric capsule, 25

14409J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	2	..	*54.19	31.60	Mayne Pharma Erythromycin [YT]

▪ **ESCITALOPRAM**


Restricted benefit

Major depressive disorders


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

escitalopram 10 mg tablet, 28

14349F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*18.89	20.34	^a APO-Escitalopram [TX] ^a Blooms Escitalopram [BG] ^a Escitalopram GH [HQ] ^a Esipram [CF] ^a LoxaLate [AF]	^a APX-Escitalopram [TY] ^a Cilopam-S [ZS] ^a Escitalopram Sandoz [HX] ^a Lexam 10 [RW] ^a NOUMED ESCITALOPRAM [VO]
			^B 28.36	*47.25	20.34	^a Lexapro [LU]	

escitalopram 20 mg tablet, 28

14415Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*18.89	20.34	^a APO-Escitalopram [TX] ^a Blooms Escitalopram [BG] ^a Escitalopram GH [HQ] ^a Esipram [CF]	^a APX-Escitalopram [TY] ^a Cilopam-S [ZS] ^a Escitalopram Sandoz [HX] ^a Lexam 20 [RW]

^a LoxaLate [AF]

^a NOUMED ESCITALOPRAM [VO]

^B29.06 *47.95 20.34 ^a Lexapro [LU]

▪ ESCITALOPRAM

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

escitalopram 10 mg tablet, 28

14519E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*18.89	20.34	^a APO-Escitalopram [TX]	^a APX-Escitalopram [TY]
						^a Blooms Escitalopram [BG]	^a Escitalopram GH [HQ]
						^a Escitalopram Sandoz [HX]	^a Esipram [CF]
						^a Lexam 10 [RW]	^a LoxaLate [AF]
						^a NOUMED ESCITALOPRAM [VO]	
			^B 28.36	*47.25	20.34	^a Lexapro [LU]	

escitalopram 20 mg tablet, 28

14416R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*18.89	20.34	^a APO-Escitalopram [TX]	^a APX-Escitalopram [TY]
						^a Blooms Escitalopram [BG]	^a Escitalopram GH [HQ]
						^a Escitalopram Sandoz [HX]	^a Esipram [CF]
						^a Lexam 20 [RW]	^a NOUMED ESCITALOPRAM [VO]
			^B 29.06	*47.95	20.34	^a Lexapro [LU]	

▪ ESCITALOPRAM

Restricted benefit

Major depressive disorders

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.

Restricted benefit

Moderate to severe generalised anxiety disorder (GAD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must be one for whom a GP Mental Health Care Plan, as described under items 2715 or 2717 of the Medicare Benefits Schedule, has been prepared.


Restricted benefit

Moderate to severe social anxiety disorder (social phobia, SAD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be defined by Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria, **AND**
- Patient must not have responded to non-pharmacological therapy, **AND**
- Patient must have been assessed by a psychiatrist.

escitalopram 20 mg/mL oral liquid, 15 mL

14546N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	2	..	*65.41	31.60	Lexapro [LU]

ESOMEPRAZOLE

Note Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Standard dose proton pump inhibitors are appropriate step-down therapy from high dose proton pump inhibitors.

Note Continuing Therapy Only:

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

Authority required

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

Authority required

Scleroderma oesophagus

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have symptoms which are inadequately controlled using a standard dose proton pump inhibitor.

esomeprazole 40 mg enteric capsule, 30

14405E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*28.07	29.52	^a Noxicid Caps [AL]

esomeprazole 40 mg enteric tablet, 30

14373L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*28.07	29.52	^a APO-Esomeprazole [TY] ^a Esomeprazole GxP [AF] ^a Esomeprazole RBX [RA] ^a ESOMEPRAZOLE-WGR [WG] ^a Nexazole [RW] ^a NOUMED ESOMEPRAZOLE [VO]	^a Esomeprazole GH [GQ] ^a Esomeprazole Mylan [AL] ^a Esomeprazole Viatris [MQ] ^a Esopreze [BG] ^a Nexole [RF]
			^B 14.00	*42.07	29.52	^a Nexium [AP]	

▪ **ESOMEPRAZOLE**

Note Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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)

15530

Gastro-oesophageal reflux disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

esomeprazole 20 mg enteric capsule, 30

14303T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	^a Noxicid Caps [AL]

esomeprazole 20 mg enteric tablet, 30

14444F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	^a APO-Esomeprazole [TY] ^a Esomeprazole GxP [AF] ^a Esomeprazole RBX [RA] ^a ESOMEPRAZOLE-WGR [WG] ^a Nexazole [RW] ^a NOUMED ESOMEPRAZOLE [VO]	^a Esomeprazole GH [GQ] ^a Esomeprazole Mylan [AL] ^a Esomeprazole Viatris [MQ] ^a Esopreze [BG] ^a Nexole [RF]
			^B 14.00	*36.07	23.52	^a Nexium [AP]	

▪ **ESOMEPRAZOLE**

Note Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

Authority required (STREAMLINED)

15658

Scleroderma oesophagus

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Authority required (STREAMLINED)

15682

Pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

esomeprazole 20 mg enteric capsule, 30

14510Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	^a Noxicid Caps [AL]

esomeprazole 20 mg enteric tablet, 30

14308C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	^a APO-Esomeprazole [TY] ^a Esomeprazole GxP [AF] ^a Esomeprazole RBX [RA] ^a ESOMEPRAZOLE-WGR [WG] ^a Nexazole [RW] ^a NOUMED ESOMEPRAZOLE [VO]	^a Esomeprazole GH [GQ] ^a Esomeprazole Mylan [AL] ^a Esomeprazole Viatris [MQ] ^a Esopreze [BG] ^a Nexole [RF]
			^B 14.00	*36.07	23.52	^a Nexium [AP]	

ESOMEPRAZOLE

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

Note The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

Note A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

Note Pharmaceutical benefits that have the form esomeprazole tablet 20 mg and pharmaceutical benefits that have the form esomeprazole capsule 20 mg are equivalent for the purposes of substitution.

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

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

Clinical criteria:

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

esomeprazole 20 mg enteric capsule, 30

14537D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*30.67	31.60	^a Noxicid Caps [AL]

esomeprazole 20 mg enteric tablet, 30

14481E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*30.67	31.60	^a APO-Esomeprazole [TY] ^a Esomeprazole GxP [AF] ^a Esomeprazole RBX [RA]	^a Esomeprazole GH [GQ] ^a Esomeprazole Mylan [AL] ^a Esomeprazole Viatris [MQ]

^a ESOMEPRAZOLE-WGR [WG] ^a Esopreze [BG]
^a Nexazole [RW] ^a Nexole [RF]
^a NOUMED ESOMEPRAZOLE
[VO]

^B28.00 *58.67 31.60 ^a Nexium [AP]

■ ESOMEPRAZOLE

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

Note The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

Note A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

Note A high dose proton pump inhibitor is: esomeprazole 40 mg.

Note Pharmaceutical benefits that have the form esomeprazole tablet 40 mg and pharmaceutical benefits that have the form esomeprazole capsule 40 mg are equivalent for the purposes of substitution.

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 This authority approval must be sought by the specified specialist prescriber.

Authority required

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract.

Clinical criteria:

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a high dose proton pump inhibitor (PPI) administered once daily, (ii) a standard dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from a high dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

esomeprazole 40 mg enteric capsule, 30

14445G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*42.67	31.60	^a Noxicid Caps [AL]

esomeprazole 40 mg enteric tablet, 30

14512T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*42.67	31.60	^a APO-Esomeprazole [TY] ^a Esomeprazole GxP [AF] ^a Esomeprazole RBX [RA] ^a ESOMEPRAZOLE-WGR [WG] ^a Nexazole [RW] ^a NOUMED ESOMEPRAZOLE [VO]	^a Esomeprazole GH [GQ] ^a Esomeprazole Mylan [AL] ^a Esomeprazole Viatris [MQ] ^a Esopreze [BG] ^a Nexole [RF]
			^B 28.00	*70.67	31.60	^a Nexium [AP]	

■ ESTRADIOL + NORETHISTERONE ACETATE

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.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

estradiol 50 microgram/24 hours + norethisterone acetate 250 microgram/24 hours patch, 8

14336M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*56.01	31.60	Estalis continuous 50/250 [SZ]

FLUOXETINE**Restricted benefit**

Major depressive disorders

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Obsessive-compulsive disorder

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

fluoxetine 20 mg capsule, 28

14548Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*20.99	22.44	^a APO-Fluoxetine [TX]	^a Blooms the Chemist Fluoxetine [BG]
						^a FLUOTEX [RF]	^a Fluoxetine APOTEX [TY]
						^a Fluoxetine generichealth [GQ]	^a Fluoxetine Sandoz [SZ]
						^a NOUMED FLUOXETINE [VO]	^a Zactin [AF]
			^b 2.38	*23.37	22.44	^a Prozac 20 [LY]	

FLUTICASONE FUROATE**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

fluticasone furoate 100 microgram/actuation powder for inhalation, 30 actuations

14515Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*47.13	31.60	Arnuity Ellipta [GK]

fluticasone furoate 200 microgram/actuation powder for inhalation, 30 actuations

14380W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*75.41	31.60	Arnuity Ellipta [GK]

FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL

Note Formal assessment and correction of inhaler technique should be performed in accordance with the COPD-X Plan (available at <http://copdx.org.au/>); the assessment and adherence to correct technique should be documented in the patient's medical records.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)**15543**

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR
- Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition.

Treatment criteria:

- Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information.

fluticasone furoate 100 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

14346C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*167.37	31.60	Trelegy Ellipta 100/62.5/25 [GK]

▪ **FLUTICASONE FUROATE + UMECLIDINIUM + VILANTEROL**

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note This pharmaceutical benefit is not for the treatment of chronic obstructive pulmonary disease (COPD).

Note This product is not indicated for the initiation of treatment in asthma

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LABA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Authority required (STREAMLINED)

15601

Severe asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

Population criteria:

- Patient must be at least 18 years of age.
Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

fluticasone furoate 200 microgram/actuation + umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

14382Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*175.57	31.60	Trelegy Ellipta 200/62.5/25 [GK]

▪ **FLUTICASONE FUROATE + VILANTEROL**

Note This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15692

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

fluticasone furoate 200 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

14345B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*135.57	31.60	Breo Ellipta 200/25 [GK]

▪ **FLUTICASONE FUROATE + VILANTEROL**

Authority required (STREAMLINED)

15546

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

Note This drug is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15548

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

fluticasone furoate 100 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

14379T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*103.53	31.60	Breo Ellipta 100/25 [GK]

FLUTICASONE PROPIONATE

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

fluticasone propionate 125 microgram/actuation inhalation, 120 actuations

14347D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*40.11	31.60	^a Axotide [TX]	^a Fluticasone Cipla Inhaler [LR]
			^b 6.00	*46.11	31.60	^a Flixotide [GK]	

fluticasone propionate 100 microgram/actuation powder for inhalation, 60 actuations

14412M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*25.19	26.64	^a Axotide Junior Accuhaler [TX]
			^b 8.00	*33.19	26.64	^a Flixotide Junior Accuhaler [GK]

fluticasone propionate 250 microgram/actuation powder for inhalation, 60 actuations

14381X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*40.11	31.60	^a Axotide Accuhaler [TX]
			^b 8.00	*48.11	31.60	^a Flixotide Accuhaler [GK]

FLUTICASONE PROPIONATE

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.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

fluticasone propionate 50 microgram/actuation inhalation, 120 actuations

14487L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*28.29	29.74	^a Axotide Junior [TX]
			^b 8.00	*36.29	29.74	^a Flixotide Junior [GK]

FLUTICASONE PROPIONATE + FORMOTEROL

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.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15635

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 12 years or over.

fluticasone propionate 50 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations

14411L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*65.11	31.60	flutiform 50/5 [MF]

fluticasone propionate 125 microgram/actuation + formoterol fumarate dihydrate 5 microgram/actuation inhalation, 120 actuations

14343X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*66.25	31.60	flutiform 125/5 [MF]

fluticasone propionate 250 microgram/actuation + formoterol fumarate dihydrate 10 microgram/actuation inhalation, 120 actuations

14344Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*89.69	31.60	flutiform 250/10 [MF]

FLUTICASONE PROPIONATE + SALMETEROL

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15604

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 4 years or older.

fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations

14544L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*71.69	31.60	^a Evocair MDI [AF]	^a Fluticasone + Salmeterol Cipla 125/25 [LR]
						^a Pavtide [TX]	^a SalplusF Inhaler 125/25 [SZ]
			^B 8.00	*79.69	31.60	^a Seretide MDI 125/25 [GK]	

fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations

14414P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*74.41	31.60	^a PAVTIDE MDI 50/25 [TX]
			^B 8.00	*82.41	31.60	^a Seretide MDI 50/25 [GK]

fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

14413N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*74.41	31.60	^a PAVTIDE ACCUHALER 100/50 [TX]
			^B 8.00	*82.41	31.60	^a Seretide Accuhaler 100/50 [GK]

FLUTICASONE PROPIONATE + SALMETEROL

Note This product is not indicated for the initiation of treatment in asthma

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15693

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

14449L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*71.69	31.60	^a Fluticasone Salmeterol Cipler 250/50 [LR]	^a PAVTIDE ACCUHALER 250/50 [TX]
						^a Salfumix Easyhaler 250/50 [OX]	^a SalplusF DPI 250/50 [SZ]
			^b 8.00	*79.69	31.60	^a Seretide Accuhaler 250/50 [GK]	

▪ **FLUTICASONE PROPIONATE + SALMETEROL**

Authority required (STREAMLINED)

15715

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Population criteria:

- Patient must be aged 4 years or older.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15548

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation, 120 actuations

14311F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*92.29	31.60	^a Evocair MDI [AF]	^a Fluticasone + Salmeterol Cipler 250/25 [LR]
						^a Pavtide [TX]	^a SalplusF Inhaler 250/25 [SZ]
			^b 8.00	*100.29	31.60	^a Seretide MDI 250/25 [GK]	

▪ **FLUTICASONE PROPIONATE + SALMETEROL**

Authority required (STREAMLINED)

15714

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**

- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.

Note This product is not indicated for the initiation of treatment in asthma

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15548

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have significant symptoms despite regular beta-2 agonist bronchodilator therapy, **AND**
- Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with LABA monotherapy or LAMA/LABA combination therapy.

Note A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

14450M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*92.29	31.60	^a Fluticasone Salmeterol Ciphaler 500/50 [LR]	^a PAVTIDE ACCUHALER 500/50 [TX]
						^a Salfumix Easyhaler 500/50 [OX]	^a SalplusF DPI 500/50 [SZ]
			^b 8.00	*100.29	31.60	^a Seretide Accuhaler 500/50 [GK]	

▪ **FLUVOXAMINE**

Restricted benefit

Major depressive disorders

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Obsessive-compulsive disorder

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

fluvoxamine maleate 100 mg tablet, 30

14314J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*30.61	31.60	^a APO-Fluvoxamine [TX]	^a Faverin 100 [RW]
						^a FLUVOXAMINE-WGR [WG]	^a Movox 100 [AF]
			^b 7.00	*37.61	31.60	^a Luvox [GO]	

fluvoxamine maleate 50 mg tablet, 30

14488M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*24.79	26.24	^a APO-Fluvoxamine [TX]	^a Faverin 50 [RW]
						^a FLUVOXAMINE-WGR [WG]	^a Movox 50 [AL]
			^b 7.00	*31.79	26.24	^a Luvox [GO]	

▪ **FORMOTEROL**

Restricted benefit

Asthma


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.


formoterol fumarate dihydrate 12 microgram powder for inhalation, 60 capsules

14419X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*47.45	31.60	Foradile [SZ]

formoterol fumarate dihydrate 12 microgram/actuation powder for inhalation, 60 actuations

14517C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*46.45	31.60	Oxis Turbuhaler [AP]


formoterol fumarate dihydrate 6 microgram/actuation powder for inhalation, 60 actuations

14547P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*35.41	31.60	Oxis Turbuhaler [AP]

■ GLYCERYL TRINITRATE**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.


glyceryl trinitrate 10 mg/24 hours patch, 30

14478B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*56.01	31.60	Minitran 10 [IL]

glyceryl trinitrate 5 mg/24 hours patch, 30

14371J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*45.91	31.60	Minitran 5 [IL]

glyceryl trinitrate 15 mg/24 hours patch, 30

14335L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*61.77	31.60	Minitran 15 [IL]

■ GLYCOPYRRONIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.


Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

glycopyrronium 50 microgram powder for inhalation, 30 capsules

14417T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*105.29	31.60	seebri breezhaler [NV]

■ HYALURONATE SODIUM

Note The in-use shelf life of Hylo-Fresh and Hylo-Forte is 6 months from the date of opening.

Authority required (STREAMLINED)


15559

Severe dry eye syndrome


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

hyaluronate sodium 0.1% eye drops, 10 mL

14354L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*56.17	31.60	Hylo-Fresh [AE]

hyaluronate sodium 0.2% eye drops, 10 mL

14494W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*56.17	31.60	Hylo-Forte [AE]

■ HYDROCORTISONE**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.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

hydrocortisone 20 mg tablet, 60

14476X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	4	..	*54.75	31.60	^a Hydrocortisone Viatris 20 [AL]
			^B 6.00	*60.75	31.60	^a Hysone 20 [AF]

■ HYPROMELLOSE

Restricted benefit

Severe dry eye syndrome

hypromellose 0.3% w/w eye drops, 10 mL

11625W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	16.17	17.62	^a In a Wink Moisturising [IQ]	^a Revive Tears [PP]
			^B 3.61	19.78	17.62	^a Genteal [AQ]	

hypromellose 0.3% w/w eye drops, 10 mL

11634H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±1	5	..	16.17	17.62	^a In a Wink Moisturising [IQ]	^a Revive Tears [PP]
			^B 3.61	19.78	17.62	^a Genteal [AQ]	

hypromellose 0.5% eye drops, 15 mL

2956N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	17.22	18.67	Methopt [AF]

hypromellose 0.5% eye drops, 15 mL

5517J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	17.22	18.67	Methopt [AF]

■ HYPROMELLOSE

Restricted benefit

Severe dry eye syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

hypromellose 0.3% w/w eye drops, 10 mL

14318N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP NP	±2	5	..	*18.89	20.34	^a In a Wink Moisturising [IQ]	^a Revive Tears [PP]
			^B 7.22	*26.11	20.34	^a Genteal [AQ]	

hypromellose 0.5% eye drops, 15 mL

14320Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	±2	5	..	*20.99	22.44	Methopt [AF]

■ HYPROMELLOSE

Note The in-use shelf life of Evolve carmellose 0.5% and Evolve hypromellose 0.3% is 3 months from the date of opening.

Authority required (STREAMLINED)

15559

Severe dry eye syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

hypromellose 0.3% w/v eye drops, 10 mL

14492R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	±2	5	..	*36.57	31.60	Evolve Hypromellose [CX]

■ HYPROMELLOSE + CARBOMER-980

Restricted benefit

Severe dry eye syndrome

hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

5519L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±1	5	..	17.37	18.82	^a HPMC PAA [IQ]
			^B 4.65	22.02	18.82	^a Genteal gel [AQ]

hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

8564R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	5	..	17.37	18.82	^a HPMC PAA [IQ]
			^B 4.65	22.02	18.82	^a Genteal gel [AQ]

■ HYPROMELLOSE + CARBOMER-980

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

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

Restricted benefit

Severe dry eye syndrome

Clinical criteria:

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

hypromellose 0.3% + carbomer-980 0.2% eye gel, 10 g

9215B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	‡1	11	..	17.37	18.82	^a HPMC PAA [IQ]
			^B 4.65	22.02	18.82	^a Genteal gel [AQ]

■ INDACATEROL

Note This drug is not PBS-subsidised for the treatment of asthma.

Note The treatment must not be used in combination with an ICS/LABA, or LAMA/LABA

Note A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note An ICS/LABA includes budesonide/formoterol, fluticasone/salmeterol, or fluticasone/vilanterol

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

indacaterol 150 microgram powder for inhalation, 30 capsules

14334K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*105.29	31.60	Onbrez [NV]

indacaterol 300 microgram powder for inhalation, 30 capsules

14368F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*105.29	31.60	Onbrez [NV]

■ INDACATEROL + GLYCOPYRRONIUM

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

Note A LAMA includes tiotropium, glycopyrronium, acclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15691

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

indacaterol 110 microgram + glycopyrronium 50 microgram powder for inhalation, 30 capsules

14504J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*162.87	31.60	ultibro breezhaler 110/50 [NV]

■ INDACATEROL + GLYCOPYRRONIUM + MOMETASONE

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note This drug is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note This product is not indicated for the initiation of treatment in asthma

Note The treatment must not be used in combination with an ICS/LABA, LABA/LAMA or LAMA, LABA or ICS monotherapy.

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note An ICS includes fluticasone propionate, fluticasone furoate, budesonide, beclometasone or ciclesonide.

Authority required (STREAMLINED)

15601

Severe asthma

Clinical criteria:


- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique.

Population criteria:


- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 136 microgram powder for inhalation, 30 capsules

14399W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*167.19	31.60	Enerzair Breezhaler [NV]

indacaterol 114 microgram + glycopyrronium 46 microgram + mometasone furoate 68 microgram powder for inhalation, 30 capsules

14471P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*133.95	31.60	Enerzair Breezhaler [NV]

■ INDACATEROL + MOMETASONE

Note This product is not indicated for the initiation of treatment in asthma

Note This product is not PBS-subsidised for the treatment of chronic obstructive pulmonary disease (COPD).

Note The patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA)

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15653

Asthma


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids.


Population criteria:

- Patient must be aged 12 years or over.


indacaterol 125 microgram + mometasone furoate 62.5 microgram powder for inhalation, 30 capsules

14332H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*62.49	31.60	Aectura Breezhaler [NV]

indacaterol 125 microgram + mometasone furoate 260 microgram powder for inhalation, 30 capsules

14441C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*105.77	31.60	Aectura Breezhaler [NV]

indacaterol 125 microgram + mometasone furoate 127.5 microgram powder for inhalation, 30 capsules

14333J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*74.11	31.60	Aectura Breezhaler [NV]

■ LANSOPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Restricted benefit

Gastro-oesophageal reflux disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Scleroderma oesophagus

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

lansoprazole 15 mg enteric capsule, 30

14448K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	
NP	2	5	..	*20.99	22.44	Zopral [AF]	

lansoprazole 15 mg orally disintegrating tablet, 28

14374M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.83	22.28	^a APO-Lansoprazole ODT [TX] ^a Zopral ODT [AF]	^a Lansoprazole ODT GH [GQ]
			^B 9.60	*30.43	22.28	^a Zoton FasTabs [PF]	

▪ **LANSOPRAZOLE**

Note Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

Authority required (STREAMLINED)

15658

Scleroderma oesophagus

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

lansoprazole 30 mg enteric capsule, 28

14340R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*23.11	24.56	^a APO-Lansoprazole [TX] ^a NOUMED LANSOPRAZOLE [VO]	^a Lanzopran [RA] ^a Zopral [AF]

lansoprazole 30 mg orally disintegrating tablet, 28

14342W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*23.11	24.56	^a APO-Lansoprazole ODT [TX] ^a Zopral ODT [AF]	^a Lansoprazole ODT GH [GQ]
			^B 10.46	*33.57	24.56	^a Zoton FasTabs [PF]	

▪ **LANSOPRAZOLE**

Note Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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)

15530

Gastro-oesophageal reflux disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

lansoprazole 30 mg enteric capsule, 28

14302R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*23.11	24.56	^a APO-Lansoprazole [TX] ^a NOUMED LANSOPRAZOLE [VO]	^a Lanzopran [RA] ^a Zopral [AF]

lansoprazole 30 mg orally disintegrating tablet, 28

14406F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*23.11	24.56	^a APO-Lansoprazole ODT [TX]	^a Lansoprazole ODT GH [GQ]
						^a Zopral ODT [AF]	
			^B 10.46	*33.57	24.56	^a Zoton FasTabs [PF]	

■ LANSOPRAZOLE

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

Note The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

Note A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

Note Pharmaceutical benefits that have the form lansoprazole capsule 30 mg and pharmaceutical benefits that have the form lansoprazole tablet 30 mg (orally disintegrating) are equivalent for the purposes of substitution.

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

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

Clinical criteria:

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

lansoprazole 30 mg enteric capsule, 28

14304W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*32.75	31.60	^a APO-Lansoprazole [TX]	^a Lanzopran [RA]
						^a NOUMED LANSOPRAZOLE [VO]	^a Zopral [AF]

lansoprazole 30 mg orally disintegrating tablet, 28

14339Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*32.75	31.60	^a APO-Lansoprazole ODT [TX]	^a Lansoprazole ODT GH [GQ]
						^a Zopral ODT [AF]	
			^B 20.92	*53.67	31.60	^a Zoton FasTabs [PF]	

■ LAROTRECTINIB

Note For a patient who has received non-PBS-subsidised supply of this drug, apply under an 'Initial treatment' phase listing provided that they meet all stated PBS eligibility criteria.

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

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Solid tumours with confirmed neurotrophic tropomyosin receptor kinase (NTRK) gene fusion

Treatment Phase: Continuing treatment

Treatment criteria:

- Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing for solid tumours (of any type) with confirmed NTRK gene fusion where treatment with this drug is/was initiated in a child; OR
- Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing for solid tumours (of certain specified types) with confirmed NTRK gene fusion which either includes: (i) mammary analogue secretory carcinoma of the salivary gland, (ii) secretory breast carcinoma.

Clinical criteria:

- The treatment must cease to be a PBS benefit upon radiographic progression, **AND**
 - The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.
- Where radiographic progression is observed, mark any remaining repeat prescriptions with the word 'cancelled'.

larotrectinib 100 mg capsule, 56

13043L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	10062.60	31.60	Vitrakvi [BN]

larotrectinib 25 mg capsule, 56

13027P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	2637.60	31.60	Vitrakvi [BN]

larotrectinib 20 mg/mL oral liquid, 2 x 50 mL

13289K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	3462.60	31.60	Vitrakvi [BN]


▪ **LATANOPROST**

Note For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

latanoprost 0.005% eye drops, 2.5 mL

14453Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±2	5	..	*22.07	23.52	^a APO-Latanoprost [TX] ^a LATANOPROST-WGR [WG] ^a Xalatan [AS]	^a Latanoprost Sandoz [SZ] ^a Xalaprost [AF]

▪ **LATANOPROST + TIMOLOL**

Note For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.


Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

latanoprost 0.005% + timolol 0.5% eye drops, 2.5 mL

14350G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±2	5	..	*29.77	31.22	^a APO-Latanoprost/Timolol 0.05/5 [TX] ^a Xalamol 50/5 [AF]	^a Xalacom [AS]

▪ **LEVODOPA + BENSERAZIDE**

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.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

levodopa 100 mg + benserazide 25 mg capsule, 100

14387F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*45.61	31.60	Madopar 125 [RO]

levodopa 100 mg + benserazide 25 mg modified release capsule, 100

14525L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*52.73	31.60	Madopar HBS [RO]

levodopa 200 mg + benserazide 50 mg capsule, 100

14551W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*65.53	31.60	Madopar [RO]

levodopa 50 mg + benserazide 12.5 mg capsule, 100

14388G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*36.89	31.60	Madopar 62.5 [RO]

levodopa 100 mg + benserazide 25 mg dispersible tablet, 100

14552X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*57.09	31.60	Madopar Rapid 125 [RO]

levodopa 50 mg + benserazide 12.5 mg dispersible tablet, 100

14356N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*36.89	31.60	Madopar Rapid 62.5 [RO]

levodopa 100 mg + benserazide 25 mg tablet, 100

14455T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*45.61	31.60	Madopar 125 [RO]

levodopa 200 mg + benserazide 50 mg tablet, 100

14428J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*65.53	31.60	Madopar [RO]

■ LEVODOPA + CARBIDOPA**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.

Restricted benefit

Parkinson disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be one in which fluctuations in motor function are not adequately controlled by frequent dosing with conventional formulations of levodopa with decarboxylase inhibitor.

levodopa 200 mg + carbidopa 50 mg modified release tablet, 100

14322T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*125.77	31.60	Sinemet CR [AL]

■ LEVODOPA + CARBIDOPA**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.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

levodopa 100 mg + carbidopa 25 mg tablet, 100

14427H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*51.43	31.60	^a APO-Levodopa/Carbidopa [TX] ^a Kinson [AF]	^a SINADOPA 100/25 [RW] ^a Sinemet 100/25 [AL]

levodopa 250 mg + carbidopa 25 mg tablet, 100

14454R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*60.29	31.60	^a APO-Levodopa/Carbidopa [TX] ^a SINADOPA 250/25 [RW]	^a Sinemet [AL]

▪ LEVODOPA + CARBIDOPA + ENTACAPONE

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.

Restricted benefit

Parkinson disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be being treated with levodopa decarboxylase inhibitor combinations, **AND**
- Patient must be experiencing fluctuations in motor function due to end-of-dose effect.

Restricted benefit

Parkinson disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be stabilised on concomitant treatment with levodopa decarboxylase inhibitor combinations and entacapone.

levodopa 100 mg + carbidopa 25 mg + entacapone 200 mg tablet, 100

14554B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	4	..	*312.99	31.60	^a Carlevent [TX] ^a Lecteva [TB]	^a L.C.E. Sandoz [HX] ^a Stalevo 100/25/200mg [SZ]

levodopa 125 mg + carbidopa 31.25 mg + entacapone 200 mg tablet, 100

14527N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	4	..	*324.55	31.60	^a Carlevent [TX] ^a Lecteva [TB]	^a L.C.E. Sandoz [HX] ^a Stalevo 125/31.25/200mg [SZ]

levodopa 150 mg + carbidopa 37.5 mg + entacapone 200 mg tablet, 100

14357P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	4	..	*341.83	31.60	^a Carlevent [TX] ^a Lecteva [TB]	^a L.C.E. Sandoz [HX] ^a Stalevo 150/37.5/200mg [SZ]

levodopa 200 mg + carbidopa 50 mg + entacapone 200 mg tablet, 100

14457X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	4	..	*368.31	31.60	^a Carlevent [TX] ^a Lecteva [TB]	^a L.C.E. Sandoz [HX] ^a Stalevo 200/50/200mg [SZ]

levodopa 50 mg + carbidopa 12.5 mg + entacapone 200 mg tablet, 100

14456W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	4	..	*284.19	31.60	^a Carlevent [TX] ^a Lecteva [TB]	^a L.C.E. Sandoz [HX] ^a Stalevo 50/12.5/200mg [SZ]

levodopa 75 mg + carbidopa 18.75 mg + entacapone 200 mg tablet, 100

14498C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	4	..	*296.83	31.60	^a Carlevent [TX] ^a Lecteva [TB]	^a L.C.E. Sandoz [HX] ^a Stalevo 75/18.75/200mg [SZ]

▪ LIQUID PARAFFIN + GLYCEROL + TYLOXAPOL + POLOXAMER-188 + TROMETAMOL HYDROCHLORIDE + TROMETAMOL + CETALKONIUM CHLORIDE

Note The in-use shelf life of Cationorm is 3 months from the date of opening.

Authority required (STREAMLINED)

15559

Severe dry eye syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

liquid paraffin + glycerol + tyloxapol + poloxamer-188 + trometamol hydrochloride + trometamol + cetalkonium chloride eye drops, 10 mL

14352J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	±2	5	..	*58.15	31.60	Cationorm [CS]

▪ LORLATINIB

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as either: (i) 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing, (ii) positive next generation sequencing (NGS) testing.

Authority required

Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

lorlatinib 25 mg tablet, 90

12096P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7112.69	31.60	Lorviqua [PF]

lorlatinib 100 mg tablet, 30

12091J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	7112.69	31.60	Lorviqua [PF]

▪ **MACROGOL-3350**

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have malignant neoplasia.

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

Restricted benefit

Chronic constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.


Restricted benefit

Faecal impaction

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

macrogol-3350 1 g/g powder for oral liquid, 510 g

14341T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*32.41	31.60	OsmoLax [KY]

▪ **MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE**

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have malignant neoplasia.

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function, **AND**
- The condition must be unresponsive to other oral therapies.

Restricted benefit

Constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be receiving palliative care.

Restricted benefit

Chronic constipation

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

Restricted benefit

Faecal impaction

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

macrogol-3350 13.125 g + sodium chloride 350.7 mg + sodium bicarbonate 178.5 mg + potassium chloride 46.6 mg powder for oral liquid, 30 sachets

14408H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±2	5	..	*28.61	30.06	^a APOHEALTH Macrogol with Electrolytes [GX]	^a APO-MACROGOL plus ELECTROLYTES [TX]
						^a Chemists' Own Macrogol with Electrolytes [RW]	^a Macrovic [RF]
						^a Molaxole [GO]	
						^b 4.24	[*] 32.85

▪ **MIANSERIN**

Caution Neutropenia and agranulocytosis are more frequent in the elderly, especially in the early months of therapy.

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.

Restricted benefit

Severe depression

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

mianserin hydrochloride 10 mg tablet, 50

14366D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*29.07	30.52	Lumin 10 [AF]

mianserin hydrochloride 20 mg tablet, 50

14505K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	2	..	*46.37	31.60	Lumin 20 [AF]

▪ **MIGALASTAT**

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

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

Note Special Pricing Arrangements apply.

Authority required

Fabry disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have at least one of: (i) documented deficiency of alpha-galactosidase enzyme activity in blood, (ii) presence of genetic mutations known to result in deficiency of alpha-galactosidase enzyme activity, **AND**
- Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant, **AND**
- Patient must have an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m², **AND**
- Patient must be male with Fabry-related renal disease confirmed by at least one of the following: (i) abnormal albuminuria of more than 20 mcg/min, as determined by 2 separate samples at least 24 hours apart, (ii) abnormal proteinuria of more than 150 mg/24 hours, (iii) albumin:creatinine ratio greater than upper limit of normal in 2 separate samples at least 24 hours apart, (iv) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; OR
- Patient must be female with Fabry-related renal disease confirmed by at least one of the following: (i) proteinuria of more than 300 mg/24 hours with clinical evidence of progression, (ii) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; OR
- Patient must have Fabry-related cardiac disease confirmed by at least one of the following: (i) left ventricular hypertrophy, as evidenced by cardiac MRI or echocardiogram data, in the absence of hypertension, (ii) significant life-threatening arrhythmia or conduction defect; OR
- Patient must have Fabry-related either: (i) ischaemic disease, (ii) cerebrovascular disease as shown on objective testing with no other cause or risk factors identified; OR
- Patient must have Fabry-related uncontrolled chronic pain despite the use of recommended doses of appropriate analgesia and antiepileptic medications for peripheral neuropathy; OR
- Patient must have significant Fabry-related gastrointestinal symptoms despite the use of the recommended doses of appropriate pharmacological therapies.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

Population criteria:

- Patient must be at least 12 years of age.

If hypertension is present in patients relying their eligibility on Fabry-related cardiac disease, the prescriber must treat it optimally for at least 6 months prior to submitting the first PBS authority application.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

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

(1) details of the proposed prescription; and

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Fabry disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by migalastat.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required

Fabry disease

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Fabry disease therapy)

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 September 2024; OR
- Patient must have previously received treatment with Enzyme Replacement Therapy for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 September 2024, **AND**
- Patient must have a documented migalastat amenable galactosidase alpha (GLA) gene variant prior to commencing treatment with this drug, **AND**

- Patient must have/have had an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m² prior to commencing treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

Population criteria:

- Patient must be at least 12 years of age.

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

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

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

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

migalstat 123 mg capsule, 14

14573B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	28076.45	31.60	Galafold [FT]

▪ **MINOCYCLINE**

Caution There are concerns about the incidence of benign intracranial hypertension associated 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.


Restricted benefit

Severe acne

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must not be responding to other tetracyclines.

minocycline 50 mg tablet, 60

14483G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*31.77	31.60	^a Akamin 50 [AF]	^a Minomycin-50 [AS]

▪ **MIRTAZAPINE**

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.


Restricted benefit

Major depressive disorders


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

mirtazapine 15 mg tablet, 30

14507M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*19.35	20.80	^a APX-Mirtazapine [TY] ^a Blooms The Chemist Mirtazapine [BG] ^a Mirtazapine Sandoz [SZ]	^a Axit 15 [AF] ^a MIRTANZA [RF] ^a MIRTAZAPINE-WGR [WG]

mirtazapine 15 mg orally disintegrating tablet, 30

14369G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*21.75	23.20	MIRTANZA ODT [RF]

mirtazapine 30 mg tablet, 30

14473R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*20.99	22.44	^a APX-Mirtazapine [TY]	^a Axit 30 [AF]

NP

^a Blooms The Chemist Mirtazapine [BG] ^a MIRTANZA [RF]
^a Mirtazapine Sandoz [SZ] ^a MIRTAZAPINE-WGR [WG]
^a NOUMED MIRTAZAPINE [VO]
^b12.02 *33.01 22.44 ^a Avanza [AL]

mirtazapine 30 mg orally disintegrating tablet, 30

14370H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*22.87	24.32	MIRTANZA ODT [RF]

NP

mirtazapine 45 mg tablet, 30

14561J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*23.69	25.14	^a APX-Mirtazapine [TY] ^a Blooms The Chemist Mirtazapine [BG] ^a Mirtazapine Sandoz [SZ] ^a NOUMED MIRTAZAPINE [VO]	^a Axit 45 [AF] ^a MIRTANZA [RF] ^a MIRTAZAPINE-WGR [WG]

NP

mirtazapine 45 mg orally disintegrating tablet, 30

14475W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*27.61	29.06	MIRTANZA ODT [RF]

NP

■ MOCLOBEMIDE

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.

Restricted benefit

Major depressive disorders

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

moclobemide 150 mg tablet, 60

14560H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*26.67	28.12	^a Amira 150 [AF] ^a Moclobemide Sandoz [SZ]	^a Clobemix [XT] ^a MOCLOBEMIDE-WGR [WG]
			^b 4.06	*30.73	28.12	^a Aurorix [GO]	

NP

moclobemide 300 mg tablet, 60

14442D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*35.49	31.60	^a Amira 300 [AF] ^a Moclobemide Sandoz [SZ]	^a Clobemix [XT] ^a MOCLOBEMIDE-WGR [WG]
			^b 4.06	*39.55	31.60	^a Aurorix 300 mg [GO]	

NP

■ MONTELUKAST

Note This drug is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

Note This drug is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for this drug will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to 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.

Authority required (STREAMLINED)

15642

Asthma

Treatment Phase: First-line prevention

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Population criteria:

- Patient must be aged 2 to 5 years inclusive.

Clinical criteria:

- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

montelukast 4 mg chewable tablet, 28

14526M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.27	23.72	^a MONTELAIR 4 [RF]	^a Montelukast APOTEX [GX]
						^a Montelukast Lupin [HQ]	^a Montelukast Mylan [AF]
						^a Montelukast Sandoz 4 [SZ]	^a Montelukast Viatrix [AL]

■ MONTELUKAST

Note This drug is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

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)**15643**

Asthma

Treatment Phase: First-line prevention

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be frequent intermittent; OR
- The condition must be mild persistent, **AND**
- The treatment must be the single preventer agent, **AND**
- The treatment must be an alternative to sodium cromoglycate; OR
- The treatment must be an alternative to nedocromil sodium.

Population criteria:

- Patient must be aged 6 to 14 years inclusive.

Authority required (STREAMLINED)**15644**

Asthma

Treatment Phase: Prevention of condition

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must be exercise-induced, **AND**
- The treatment must be as an alternative to adding salmeterol xinafoate; OR
- The treatment must be an alternative to adding formoterol fumarate, **AND**
- The condition must be otherwise well controlled while receiving optimal dose inhaled corticosteroid, **AND**
- Patient must require short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms.

Population criteria:

- Patient must be aged 6 to 14 years inclusive.

montelukast 5 mg chewable tablet, 28

14553Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	^a MONTELAIR 5 [RF]	^a Montelukast APOTEX [GX]
						^a Montelukast Lupin [HQ]	^a Montelukast Mylan [AF]
						^a Montelukast Sandoz 5 [SZ]	^a Montelukast Viatrix [AL]

■ NIZATIDINE

Note *Helicobacter pylori* eradication therapy should be considered prior to commencing initial treatment of peptic ulcer with this drug.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

nizatidine 150 mg capsule, 60

14306Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer	
NP	2	5	..	*34.35	31.60	^a Nizac [RF]	^a Tacidine [AF]	
				^B 15.18	*49.53	31.60	^a Tazac [RW]	

nizatidine 300 mg capsule, 30

14372K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer	
NP	2	5	..	*34.35	31.60	^a Nizac [RF]	^a Tacidine [AF]	
				^B 15.18	*49.53	31.60	^a Tazac [RW]	

■ OMEPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Restricted benefit

Gastro-oesophageal reflux disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Scleroderma oesophagus

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Zollinger-Ellison syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

omeprazole 10 mg enteric tablet, 30

14432N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*20.99	22.44	Losec Tablets [PB]

■ OMEPRAZOLE

Note Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

Authority required (STREAMLINED)**15658**

Scleroderma oesophagus

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Authority required (STREAMLINED)**15678**

Zollinger-Ellison syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

omeprazole 20 mg enteric tablet, 30

14364B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	^a APO-Omeprazole [TX] ^a Ozmepr [RW]	^a Maxor EC Tabs [AF]

omeprazole 20 mg enteric tablet, 30

14397R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	^a Acimax Tablets [FJ] ^a Omeprazole Sandoz [SZ] ^a Losec Tablets [PB]	^a Omepral [FQ]
			^b 14.30	*36.37	23.52		

omeprazole 20 mg enteric capsule, 30

14559G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	^a APO-Omeprazole [TX] ^a Omeprazole Sandoz [HX] ^a Pharmacor Omeprazole 20 [CR]	^a Maxor [AF] ^a Pemzo [RW] ^a Probitor [SZ]

■ OMEPRAZOLE

Note Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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)**15530**

Gastro-oesophageal reflux disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

omeprazole 20 mg enteric tablet, 30

14533X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	^a APO-Omeprazole [TX] ^a Ozmepr [RW]	^a Maxor EC Tabs [AF]

omeprazole 20 mg enteric tablet, 30

14557E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	^a Acimax Tablets [FJ] ^a Omeprazole Sandoz [SZ]	^a Omepral [FQ]
			^B 14.30	*36.37	23.52	^a Losec Tablets [PB]	

omeprazole 20 mg enteric capsule, 30

14464G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*22.07	23.52	^a APO-Omeprazole [TX] ^a Omeprazole Sandoz [HX] ^a Pharmacor Omeprazole 20 [CR]	^a Maxor [AF] ^a Pemzo [RW] ^a Probitor [SZ]

■ OMEPRAZOLE

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

Note The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

Note A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

Note Pharmaceutical benefits that have the forms omeprazole tablet 20 mg, omeprazole capsule 20 mg and omeprazole tablet 20 mg (as magnesium) are equivalent for the purposes of substitution.

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

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

Clinical criteria:

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

omeprazole 20 mg enteric tablet, 30

14363Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*30.67	31.60	^a Acimax Tablets [FJ]	^a Omepral [FQ]

						a Omeprazole Sandoz [SZ]	
		b28.60		*59.27		31.60	
						a Losec Tablets [PB]	
omeprazole 20 mg enteric tablet, 30							
14558F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*30.67	31.60	a APO-Omeprazole [TX]	a Maxor EC Tabs [AF]
						a Ozmp [RW]	
omeprazole 20 mg enteric capsule, 30							
14465H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*30.67	31.60	a APO-Omeprazole [TX]	a Maxor [AF]
						a Omeprazole Sandoz [HX]	
						a Pharmacor Omeprazole 20 [CR]	
						a Pemzo [RW]	
						a Probitor [SZ]	

■ OXCARBAZEPINE

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)

14932

Seizures

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have partial epileptic seizures; OR
- Patient must have primary generalised tonic-clonic seizures, **AND**
- The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs.

oxcarbazepine 150 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14562K	2	5	..	*99.91	31.60	Trileptal [NV]

NP

■ PANTOPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Restricted benefit

Gastro-oesophageal reflux disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Scleroderma oesophagus

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Zollinger-Ellison syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

pantoprazole 20 mg enteric tablet, 30

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
14501F	2	5	..	*18.89	20.34	a APO-Pantoprazole [TX]	a BTC Pantoprazole [BG]
						a NOUMED PANTOPRAZOLE [VO]	
						a Panthron [ZS]	
						a Pantoprazole generichealth [HQ]	
						a PANTOPRAZOLE-WGR [WG]	
						a Somac [NQ]	
						a Ozpan [RA]	
						a Pantoprazole APOTEX [TY]	
						a Pantoprazole Sandoz [SZ]	
						a Salpraz [AF]	
						a Sozol [RW]	

NP

■ PANTOPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

Authority required (STREAMLINED)

15658

Scleroderma oesophagus

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Authority required (STREAMLINED)


15678

Zollinger-Ellison syndrome


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

pantoprazole 40 mg enteric coated granules, 30 sachets

14466J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*55.71	31.60	Somac [NQ]

pantoprazole 40 mg enteric tablet, 30

14330F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*19.65	21.10	^a APO-Pantoprazole [TX] ^a BTC Pantoprazole [BG] ^a NOUMED PANTOPRAZOLE [VO] ^a Panthron [ZS] ^a Pantoprazole generichealth [HQ] ^a PANTOPRAZOLE-WGR [WG] ^a Somac [NQ]	^a APX-PANTOPRAZOLE [TW] ^a I-Pantoprazole [CR] ^a Ozpan [RA] ^a Pantoprazole APOTEX [TY] ^a Pantoprazole Sandoz [SZ] ^a Salpraz [AF] ^a Sozol [RW]

■ **PANTOPRAZOLE**

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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)


15530

Gastro-oesophageal reflux disease


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

pantoprazole 40 mg enteric coated granules, 30 sachets

14500E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*55.71	31.60	Somac [NQ]

pantoprazole 40 mg enteric tablet, 30

14362X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*19.65	21.10	^a APO-Pantoprazole [TX] ^a BTC Pantoprazole [BG] ^a NOUMED PANTOPRAZOLE [VO] ^a Panthron [ZS] ^a Pantoprazole generichealth [HQ] ^a PANTOPRAZOLE-WGR [WG] ^a Somac [NQ]	^a APX-PANTOPRAZOLE [TW] ^a I-Pantoprazole [CR] ^a Ozpan [RA] ^a Pantoprazole APOTEX [TY] ^a Pantoprazole Sandoz [SZ] ^a Salpraz [AF] ^a Sozol [RW]

■ **PANTOPRAZOLE**

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

Note The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

Note A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

Clinical criteria:

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR
- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

pantoprazole 40 mg enteric coated granules, 30 sachets

14395P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*97.95	31.60	Somac [NQ]

pantoprazole 40 mg enteric tablet, 30


14394N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*25.83	27.28	^a APO-Pantoprazole [TX] ^a BTC Pantoprazole [BG] ^a NOUMED PANTOPRAZOLE [VO] ^a Panthron [ZS] ^a Pantoprazole generichealth [HQ] ^a PANTOPRAZOLE-WGR [WG] ^a Somac [NQ]	^a APX-PANTOPRAZOLE [TW] ^a I-Pantoprazole [CR] ^a Ozpan [RA] ^a Pantoprazole APOTEX [TY] ^a Pantoprazole Sandoz [SZ] ^a Salpraz [AF] ^a Sozol [RW]

▪ **PARAFFIN**


Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

paraffin 1 g/g eye ointment, 2 x 3.5 g

14493T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*28.23	29.68	Poly Visc [IQ]
			^B 2.18	*30.41	29.68	Refresh Night Time [VE]

paraffin 1 g/g eye ointment, 3.5 g

14353K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*28.87	30.32	Poly Visc [IQ]

▪ **PAROXETINE**

Restricted benefit

Major depressive disorders

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Obsessive-compulsive disorder

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Panic disorder

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

paroxetine 20 mg tablet, 30

14367E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*20.99	22.44	^a APO-Paroxetine [TX]	^a APX-Paroxetine [TY]
						^a Blooms The Chemist Paroxetine [BG]	^a Extine 20 [RW]
						^a Noumed Paroxetine [VO]	^a Paroxetine GH [GQ]
						^a Paroxetine Sandoz [SZ]	^a PAROXETINE-WGR [WG]
						^a Paxtine [AF]	
			^B 5.16	*26.15	22.44	^a Aropax [AS]	

PERFLUOROHEXYLOCTANE**Note** The in-use shelf life of Novatears is 6 months from the date of opening.**Authority required (STREAMLINED)****15559**

Severe dry eye syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

perfluorohexyloctane 100% eye drops, 3 mL

14424E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	2	5	..	*54.33	31.60	Novatears [AE]

PILOCARPINE**Note** For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.**Restricted benefit**

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

pilocarpine hydrochloride 1% eye drops, 15 mL

14355M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*24.09	25.54	Isopto Carpine [NV]

pilocarpine hydrochloride 2% eye drops, 15 mL

14523J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*26.27	27.72	Isopto Carpine [NV]

pilocarpine hydrochloride 4% eye drops, 15 mL

14550T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP	±2	5	..	*31.23	31.60	Isopto Carpine [NV]

POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**Restricted benefit**

Severe dry eye syndrome

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

5524R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
OP	±1	5	..	15.98	17.43	^a Optix [PP]	^a Systane [AQ]

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

8676P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	±1	5	..	15.98	17.43	^a Optix [PP]	^a Systane [AQ]

POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**Restricted benefit**

Severe dry eye syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 15 mL

14421B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	±2	5	..	*18.51	19.96	^a Optix [PP]	^a Systane [AQ]

■ POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL**Authority required (STREAMLINED)****15559**

Severe dry eye syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses

14520F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*55.35	31.60	Systane [AQ]	

■ PRAMIPEXOLE**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

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.

Restricted benefit

Parkinson disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

pramipexole dihydrochloride monohydrate 1 mg tablet, 100

14532W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*143.93	31.60	^a APO-Pramipexole [TX] ^a Simipex 1 [RW]	^a Sifrol [BY] ^a Simpral [AF]

pramipexole dihydrochloride monohydrate 250 microgram tablet, 100

14329E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*43.03	31.60	^a APO-Pramipexole [TX] ^a Simipex 0.25 [RW]	^a Sifrol [BY] ^a Simpral [AF]

■ PRAMIPEXOLE**Caution** Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

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 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.

Restricted benefit

Parkinson disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

pramipexole dihydrochloride monohydrate 375 microgram modified release tablet, 30

14324X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*28.99	30.44	^a APO-Pramipexole ER [TX] ^a SIMIPEX XR [RW]	^a Sifrol ER [BY]

pramipexole dihydrochloride monohydrate 750 microgram modified release tablet, 30

14459B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*44.01	31.60	^a APO-Pramipexole ER [TX] ^a SIMIPEX XR [RW]	^a Sifrol ER [BY]

pramipexole dihydrochloride monohydrate 1.5 mg modified release tablet, 30

14360T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*74.55	31.60	^a APO-Pramipexole ER [TX]	^a Sifrol ER [BY]

^a SIMIPEX XR [RW]

pramipexole dihydrochloride monohydrate 3 mg modified release tablet, 30

14460C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*148.39	31.60	^a APO-Pramipexole ER [TX] ^a SIMIPEX XR [RW]	^a Sifrol ER [BY]

pramipexole dihydrochloride monohydrate 2.25 mg modified release tablet, 30

14556D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*105.07	31.60	^a APO-Pramipexole ER [TX] ^a SIMIPEX XR [RW]	^a Sifrol ER [BY]

pramipexole dihydrochloride monohydrate 3.75 mg modified release tablet, 30

14461D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*180.43	31.60	^a APO-Pramipexole ER [TX] ^a SIMIPEX XR [RW]	^a Sifrol ER [BY]

pramipexole dihydrochloride monohydrate 4.5 mg modified release tablet, 30

14325Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*218.33	31.60	^a APO-Pramipexole ER [TX] ^a SIMIPEX XR [RW]	^a Sifrol ER [BY]

▪ **PYRIDOSTIGMINE**

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

pyridostigmine bromide 10 mg tablet, 50

14392L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*39.27	31.60	Mestinon [IL]

pyridostigmine bromide 180 mg modified release tablet, 50

14462E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*180.71	31.60	Mestinon Timespan [IL]

pyridostigmine bromide 60 mg tablet, 150

14529Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*88.03	31.60	Mestinon [IL]

▪ **RABEPRAZOLE**

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Restricted benefit

Gastro-oesophageal reflux disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Scleroderma oesophagus

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

rabeprazole sodium 10 mg enteric tablet, 28

14502G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*20.63	22.08	^a APO-Rabeprazole [TX] ^a Rabeprazole Sandoz [SZ]	^a Parbezol [RW] ^a RABEPRAZOLE-WGR [WG]
			^B 10.02	*30.65	22.08	^a Pariet [JC]	

▪ **RABEPRAZOLE**

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

Authority required (STREAMLINED)

15658

Scleroderma oesophagus

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

rabeprazole sodium 20 mg enteric tablet, 30

14433P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.63	22.08	^a APO-Rabeprazole [TX] ^a Parbezol [RW] ^a Rabeprazole Sandoz [SZ] ^a RABEPRAZOLE-WGR [WG]	^a Noumed Rabeprazole [VO] ^a Rabeprazole Mylan [AF] ^a Rabeprazole SUN [RN] ^a Zabep [AL]
			^B 10.02	*30.65	22.08	^a Pariet [JC]	

■ RABEPRAZOLE

Note Check patient adherence to lower dose proton pump inhibitor before "stepping-up" therapy.

Note Low dose proton pump inhibitors are appropriate step-down therapy from standard dose proton pump inhibitors.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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)**15530**

Gastro-oesophageal reflux disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for long-term maintenance of gastro-oesophageal reflux disease in a patient with symptoms inadequately controlled using a low dose proton pump inhibitor.

rabeprazole sodium 20 mg enteric tablet, 30

14463F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*20.63	22.08	^a APO-Rabeprazole [TX] ^a Parbezol [RW] ^a Rabeprazole Sandoz [SZ] ^a RABEPRAZOLE-WGR [WG]	^a Noumed Rabeprazole [VO] ^a Rabeprazole Mylan [AF] ^a Rabeprazole SUN [RN] ^a Zabep [AL]
			^B 10.02	*30.65	22.08	^a Pariet [JC]	

■ RABEPRAZOLE

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

Note The treatment must not be prescribed under this restriction for any of the following PBS-indications: (i) gastro-oesophageal reflux disease (where the word 'complex' is absent), (ii) scleroderma oesophagus, (iii) pathological hypersecretory conditions including Zollinger-Ellison syndrome and idiopathic hypersecretion, (iv) peptic ulcer, (v) eradication of **Helicobacter pylori**.

Note A standard dose proton pump inhibitor is one of: esomeprazole 20 mg, lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg.

Note A low dose proton pump inhibitor includes: lansoprazole 15mg, omeprazole 10mg, pantoprazole 20mg and rabeprazole 10mg.

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

Complex gastro-oesophageal reflux disease (GORD)

Treatment Phase: One of: (1) establishment of symptom control, (2) maintenance treatment, (3) re-establishment of symptom control

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Treatment criteria:

- Must be treated by a gastroenterologist; OR
- Must be treated by a surgeon with expertise in the upper gastrointestinal tract; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialists in relation to this current PBS benefit being sought, with the specialist's name documented in the patient's medical records for auditing purposes; OR
- Must be treated by a medical practitioner who has not consulted a specialist, but only if treatment continues therapy initiated under this restriction with involvement by a specialist (i.e. continuing treatment initiated for non-complex GORD does not meet this criterion), with the specialist's name documented in the patient's medical records for auditing purposes.

Clinical criteria:

- The treatment must be: (i) the sole PBS-subsidised proton pump inhibitor (PPI) for this condition, (ii) the sole strength of this PPI, (iii) the sole form of PPI, **AND**
- Patient must have symptoms inadequately controlled with each of: (i) a standard dose proton pump inhibitor (PPI) administered once daily, (ii) a low dose PPI administered twice daily; treatment is for: (1) establishment of symptom control; OR
- Patient must be assessed for the risks/benefits of a step-down in dosing from standard dose PPI administered twice daily, with the determination being that the risks outweigh the benefits; treatment is for: (2) maintenance treatment; OR

- Patient must have trialled a step-down in dosing, yet symptoms have re-emerged/worsened; treatment is for: (3) re-establishment of symptom control; OR
- Patient must have trialled a step-down in dosing, with symptoms adequately managed with once daily dosing; treatment is for: (2) maintenance treatment, but with the quantity sought in this authority application being up to 1 pack per dispensing.

Check patient adherence to any preceding PPI treatment regimen. Exclude non-adherence as a cause of inadequate control before accessing treatment under this restriction.

rabeprazole sodium 20 mg enteric tablet, 30

14396Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*27.79	29.24	^a APO-Rabeprazole [TX] ^a Parbezol [RW] ^a Rabeprazole Sandoz [SZ] ^a RABEPRAZOLE-WGR [WG]	^a Noumed Rabeprazole [VO] ^a Rabeprazole Mylan [AF] ^a Rabeprazole SUN [RN] ^a Zabep [AL]
			^B 20.04	*47.83	29.24	^a Pariet [JC]	

■ RASAGILINE

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

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


Restricted benefit

Parkinson disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

rasagiline 1 mg tablet, 30

14458Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*70.01	31.60	^a Alziras [RW] ^a Rasagiline Lupin [HQ] ^a Rasagiline-Teva [EV]	^a Pharmacor Rasagiline [CR] ^a Rasagiline Sandoz [SZ] ^a RASAGILINE-WGR [WG]
			^B 7.20	*77.21	31.60	^a Azilect [TB]	

■ REBOXETINE

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.


Restricted benefit

Major depressive disorders

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

reboxetine 4 mg tablet, 60

14474T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	2	..	*66.89	31.60	Edronax [PF]

■ RILUZOLE

Note Continuing Therapy Only:

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

Authority required


Amyotrophic lateral sclerosis

Treatment Phase: Continuing treatment


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be ambulatory; OR
- Patient must not be ambulatory, and must be able to either use upper limbs or to swallow, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

riluzole 50 mg/10 mL oral liquid, 300 mL

14429K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*402.63	31.60	Teglutik [CS]

riluzole 50 mg tablet, 56

14393M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*264.29	31.60	^a APO-Riluzole [TX] ^a Rilutek [SW]	^a Pharmacor Riluzole [CR] ^a Riluzole Sandoz [SZ]

▪ ROTIGOTINE**Restricted benefit**

Parkinson disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

rotigotine 8 mg/24 hours patch, 28

14359R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*213.77	31.60	Neupro [UC]

rotigotine 4 mg/24 hours patch, 28

14326B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*171.19	31.60	Neupro [UC]

rotigotine 6 mg/24 hours patch, 28

14431M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*193.11	31.60	Neupro [UC]

▪ ROTIGOTINE**Restricted benefit**

Parkinson disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

rotigotine 2 mg/24 hours patch, 28

14327C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*130.53	31.60	Neupro [UC]


▪ SAFINAMIDE**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Restricted benefit**

Parkinson disease


Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

safinamide 50 mg tablet, 30

14391K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*112.95	31.60	Xadago [CS]

safinamide 100 mg tablet, 30

14528P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*217.35	31.60	Xadago [CS]

▪ SALMETEROL**Restricted benefit**

Asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must experience frequent episodes of the condition, **AND**
- Patient must be currently receiving treatment with oral corticosteroids; OR
- Patient must be currently receiving treatment with optimal doses of inhaled corticosteroids.

salmeterol 50 microgram/actuation powder for inhalation, 60 actuations

14328D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*47.45	31.60	Serevent Accuhaler [GK]

■ SECUKINUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 20 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 20 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 20 weeks treatment.

Treatment criteria:

- Must be treated by a dermatologist.

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

14164L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1405.07	31.60	Cosentyx [NV]

■ SECUKINUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of

biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment.

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

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the Hidradenitis Suppurativa Clinical Response (HiSCR) result.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 June 2024, **AND**
- Patient must have had a Hurley stage II or III with an abscess and inflammatory nodule (AN) count greater than or equal to 3 prior to starting treatment with this drug for this condition, **AND**
- Patient must have demonstrated a response to treatment by achieving Hidradenitis Suppurativa Clinical Response (HiSCR) after 16 weeks of treatment if the patient has been treated with this drug for this condition for 16 weeks or longer, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

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

Assessment of disease severity must not have been more than 4 weeks old at the time treatment with this drug was initiated.

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

- (a) details of the proposed prescription; and
 - (b) completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
 - (i) the Hurley stage grading; and
 - (ii) the AN count; and
 - (iii) the name of the antibiotic/s received for two separate courses each of three months; or
 - (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics
 - (v) the Hidradenitis Suppurativa Clinical Response (HiSCR) result if the patient has received 16 weeks or more of treatment.
- A patient may qualify for PBS-subsidised treatment under this restriction once only.

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

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

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

14146M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1405.07	31.60	Cosentyx [NV]

▪ SECUKINUMAB

Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

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

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

(1) details of the proposed prescription(s); and

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

(i) the Hurley stage grading; and

(ii) the AN count; and

(iii) the name of the antibiotic/s received for two separate courses each of three months; or

(iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.

The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

Details of two completed prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

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

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

- (1) details of the proposed prescription(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
 - (i) the Hurley stage grading; and
 - (ii) the AN count.

Details of two completed prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

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

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

- (1) details of the proposed prescription(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
 - (i) the Hurley stage grading; and
 - (ii) the AN count.

Details of two completed prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

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

14161H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	3	..	1405.07	31.60	Cosentyx [NV]

■ SECUKINUMAB**Note TREATMENT OF PATIENTS WITH MODERATE TO SEVERE HIDRADENITIS SUPPURATIVA**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for patient with the indication of moderate to severe hidradenitis suppurativa.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Moderate to Severe Hidradenitis Suppurativa.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab prior to 1 June 2024 is considered to start their first cycle as of 1 June 2024.

Where treatment has resulted in an inadequate response on 3 occasions, a treatment cycle is considered to have been completed, and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication 'moderate to severe hidradenitis suppurativa' before starting a new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle, and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

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

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for moderate to severe hidradenitis suppurativa.

(2) Grandfather patients (secukinumab only).

A patient who commenced treatment with secukinumab for moderate to severe hidradenitis suppurativa prior to 1 June 2024 and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this restriction. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing/swapping therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior antibiotic use. A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurement of abscess and inflammatory nodule (AN) count submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior antibiotic courses need not be re-trialled.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

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

Note Special Pricing Arrangements apply.

Authority required

Moderate to severe hidradenitis suppurativa

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR
- Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR
- Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

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

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

- (1) details of the proposed prescription(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
 - (i) the Hurley stage grading; and
 - (ii) the AN count; and
 - (iii) the name of the antibiotic/s received for two separate courses each of three months; or
 - (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics.

The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.

This restriction is intended for induction dosing only.

Details of two completed prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have had 3 treatment failures within this treatment cycle to PBS-subsidised biological medicines for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

An application for a patient who has received PBS-subsidised treatment with this drug, has not experienced treatment failure, and wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

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

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

- (1) details of the proposed prescription(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

- (i) the Hurley stage grading; and
- (ii) the AN count.

Details of two completed prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

This restriction is intended for induction dosing only.

Authority required

Moderate to severe hidradenitis suppurativa

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

Clinical criteria:

- Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3, **AND**
- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must not receive more than 20 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a dermatologist.

Assessment of disease severity must be no more than 4 weeks old at the time of application.

A response to treatment is defined as:

Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

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

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

- (1) details of the proposed prescription(s); and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

- (i) the Hurley stage grading; and
- (ii) the AN count.

Details of two completed prescriptions should be submitted with every initial application for this drug.

One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats.

This restriction is intended for induction dosing only.

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

14154Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	*5428.87	31.60	Cosentyx [NV]

▪ **SELEGILINE**

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.

Restricted benefit

Late stage Parkinson disease

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be as adjunctive therapy to a levodopa-decarboxylase inhibitor combination.

selegiline hydrochloride 5 mg tablet, 100

14430L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*94.09	31.60	Eldepryl [OX]

NP

▪ **SERTRALINE**

Restricted benefit

Major depressive disorders

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

sertraline 100 mg tablet, 30

14506L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*18.89	20.34	^a APO-Sertraline [TX]	^a Blooms The Chemist Sertraline [BG]
						^a Eleva 100 [AF]	^a NOUMED SERTRALINE [VO]
						^a Sertra 100 [RW]	^a Sertraline generichealth [GQ]
						^a Sertraline Sandoz [SZ]	^a SERTRALINE-WGR [WG]
						^a Setrona [RA]	
			^B 13.56	[*] 32.45	20.34	^a Zoloft [UJ]	

sertraline 50 mg tablet, 30

14400X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*18.89	20.34	^a APO-Sertraline [TX]	^a Blooms The Chemist Sertraline [BG]
						^a Eleva 50 [AF]	^a NOUMED SERTRALINE [VO]
						^a Sertra 50 [RW]	^a Sertraline generichealth [GQ]
						^a Sertraline Sandoz [SZ]	^a SERTRALINE-WGR [WG]
						^a Setrona [RA]	
			^B 13.56	[*] 32.45	20.34	^a Zoloft [UJ]	

▪ SERTRALINE**Restricted benefit**

Obsessive-compulsive disorder

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Restricted benefit

Panic disorder

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The treatment must be for use when other treatments have failed; OR
- The treatment must be for use when other treatments are inappropriate.

sertraline 100 mg tablet, 30

14404D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*18.89	20.34	^a APO-Sertraline [TX]	^a Blooms The Chemist Sertraline [BG]
						^a Eleva 100 [AF]	^a NOUMED SERTRALINE [VO]
						^a Sertra 100 [RW]	^a Sertraline generichealth [GQ]
						^a Sertraline Sandoz [SZ]	^a SERTRALINE-WGR [WG]
						^a Zoloft [UJ]	
			^B 13.56	[*] 32.45	20.34		

sertraline 50 mg tablet, 30

14403C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*18.89	20.34	^a APO-Sertraline [TX]	^a Blooms The Chemist Sertraline [BG]
						^a Eleva 50 [AF]	^a NOUMED SERTRALINE [VO]
						^a Sertra 50 [RW]	^a Sertraline generichealth [GQ]
						^a Sertraline Sandoz [SZ]	^a SERTRALINE-WGR [WG]
						^a Zoloft [UJ]	
			^B 13.56	[*] 32.45	20.34		

▪ SOY LECITHIN + TOCOPHEROL + VITAMIN A**Authority required (STREAMLINED)****15559**

Severe dry eye syndrome

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must be sensitive to preservatives in multi-dose eye drops.

soy lecithin 1% + tocopherol 0.002% + vitamin A palmitate 0.025% spray, 100 actuations

14426G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
OP NP	4	5	..	*57.55	31.60	tearsagain [RB]

▪ TERIPARATIDE**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** Up to a maximum of 18 pens will be reimbursed through the PBS.**Authority required (STREAMLINED)**

15536

Severe established osteoporosis

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- The treatment must not exceed a lifetime maximum of 18 months therapy.

Treatment criteria:

- Must be treated by a specialist; OR
- Must be treated by a consultant physician.

teriparatide 250 microgram/mL injection, 2.4 mL pen device

14482F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	2	..	*346.15	31.60	^a Teriparatide Lupin [GQ]	^a Terrosa [FX]

▪ TESTOSTERONE**Authority required**

Androgen deficiency

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have an established pituitary or testicular disorder.

Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum area.
The name of the specialist must be included in the authority application.

Authority required

Androgen deficiency

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must not have an established pituitary or testicular disorder, **AND**
- The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs.

Population criteria:

- Patient must be aged 40 years or older.

Treatment criteria:

- Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum area.

Androgen deficiency is defined as:

(i) testosterone level of less than 6 nmol per litre; OR

(ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonadal reference range for young men, or greater than 14 IU per litre, whichever is higher).

Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings.

The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated.

The name of the specialist must be included in the authority application.

Authority required

Micropenis

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum area.
The name of the specialist must be included in the authority application.

Authority required

Pubertal induction

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum area.

The name of the specialist must be included in the authority application.

Authority required

Constitutional delay of growth or puberty

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists.

Clinical criteria:

- The treatment must be applied to the scrotum area.

The name of the specialist must be included in the authority application.

testosterone 5% (50 mg/mL) cream, 50 mL

14563L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	1	..	*206.03	31.60	AndroForte 5 [LX]

▪ **TETRABENAZINE**

Note Continuing Therapy Only:

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

Authority required (STREAMLINED)


15673

Hyperkinetic extrapyramidal disorders

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

tetrabenazine 25 mg tablet, 112

14390J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*464.49	31.60	^a iNova Pharmaceuticals (Australia) Pty Ltd [IL]	^a Tetrabenazine SUN [RA]

▪ **TIOTROPIUM**

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Restricted benefit

Severe asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma, which required systemic corticosteroid treatment despite each of: (i) receiving optimised asthma therapy, (ii) being assessed for adherence to therapy, (iii) being assessed for correct inhaler technique,

AND


- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

Population criteria:

- Patient must be at least 18 years of age.

Optimised asthma therapy includes adherence to the maintenance combination of an inhaled corticosteroid (at least 800 micrograms budesonide per day or equivalent) and a long acting beta-2 agonist.

tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

14323W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*75.45	31.60	Spiriva Respimat [BY]

■ TIOTROPIUM**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 Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.humanservices.gov.au or www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)**15754**

Severe asthma

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

Treatment criteria:

- Must be treated by a respiratory physician, paediatric respiratory physician, clinical immunologist, allergist, paediatrician or general physician experienced in the management of patients with severe asthma; or in consultation with one of these specialists.


Clinical criteria:

- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented, **AND**
- Patient must have experienced at least one severe exacerbation prior to receiving PBS-subsidised treatment with this drug for this condition, which has required documented use of systemic corticosteroids in the previous 12 months while receiving optimised asthma therapy; OR
- Patient must have experienced frequent episodes of moderate asthma exacerbations prior to receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be used in combination with a maintenance combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA) unless a LABA is contraindicated.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.
- Optimised asthma therapy includes adherence to the maintenance combination of a medium to high dose ICS and a LABA. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative

tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

14531T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*75.45	31.60	Spiriva Respimat [BY]

■ TIOTROPIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit


Bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease

Treatment Phase: Long-term maintenance treatment

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

tiotropium 2.5 microgram/actuation inhalation solution, 60 actuations

14499D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*75.45	31.60	Spiriva Respimat [BY]

■ TIOTROPIUM

Note Pharmaceutical benefits that have the form tiotropium 18 microgram powder for inhalation and pharmaceutical benefits that have the form tiotropium 13 microgram powder for inhalation are equivalent for the purposes of substitution.

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

tiotropium 18 microgram powder for inhalation, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14576E	1	5	..	39.57	31.60	^a Tiotropium Lupin [GQ]

NP

▪ **TIOTROPIUM**

Note Pharmaceutical benefits that have the form tiotropium 18 microgram powder for inhalation and pharmaceutical benefits that have the form tiotropium 13 microgram powder for inhalation are equivalent for the purposes of substitution.

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes aclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

tiotropium 18 microgram powder for inhalation, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14361W	2	5	..	*75.45	31.60	^a Spiriva [BY]

NP

tiotropium 18 microgram powder for inhalation, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14574C	2	5	..	*65.69	31.60	^a Tiotropium Lupin [GQ]

NP

tiotropium 13 microgram powder for inhalation, 30 capsules

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14555C	2	5	..	*65.69	31.60	^a Braltus [TB]

NP

▪ **TIOTROPIUM + OLODATEROL**

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

Note A LAMA includes tiotropium, glycopyrronium, aclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15691

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

tiotropium 2.5 microgram/actuation + olodaterol 2.5 microgram/actuation inhalation solution, 60 actuations

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
14530R	±2	5	..	*137.77	31.60	Spiolto Respiimat [BY]

NP

▪ TRANYLCYPROMINE

Caution This drug is an irreversible monoamine oxidase inhibitor.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

tranylcypromine 10 mg tablet, 50

14401Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	1	..	*90.11	31.60	Parnate [GH]


▪ TRAVOPROST

Note For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

travoprost 0.004% eye drops, 2.5 mL

14549R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*52.93	31.60	Travatan [NV]

▪ TRAVOPROST + TIMOLOL

Note For Optometrists, prescribe in accordance with Optometry Board of Australia guidelines.


Restricted benefit

Elevated intra-ocular pressure

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- The condition must have been inadequately controlled with monotherapy, **AND**
- Patient must have open-angle glaucoma; OR
- Patient must have ocular hypertension.

travoprost 0.004% + timolol 0.5% eye drops, 2.5 mL

14316L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*58.83	31.60	Duotrav [NV]

▪ UMECLIDINIUM

Note The treatment must not be used in combination with a LAMA/LABA or SAMA

Note A LAMA/LABA includes acclidinium/formoterol, glycopyrronium/indacaterol, tiotropium/olodaterol, or umeclidinium/vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.


Restricted benefit

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

umeclidinium 62.5 microgram/actuation inhalation: powder for, 30 actuations

14389H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	±2	5	..	*110.13	31.60	Incruse Ellipta [GK]

▪ UMECLIDINIUM + VILANTEROL

Note This product is not PBS-subsidised for the treatment of asthma.

Note This product is not indicated for the initiation of bronchodilator therapy in COPD.

Note The treatment must not be used in combination with an ICS/LABA, LAMA, LABA, or SAMA

Note A LAMA includes tiotropium, glycopyrronium, acclidinium or umeclidinium.

Note A LABA includes olodaterol, indacaterol, salmeterol, formoterol or vilanterol.

Note A SAMA includes ipratropium

Note Diagnosis of COPD should include measurement of airflow obstruction using spirometry, with confirmation of post-bronchodilator airflow obstruction.

Note Adherence to current treatment and device (inhaler) technique should be reviewed at each clinical visit and before "stepping up" a patient's medication regimen.

Authority required (STREAMLINED)

15691

Chronic obstructive pulmonary disease (COPD)

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient, **AND**
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting muscarinic antagonist (LAMA); OR
- Patient must have COPD symptoms that persist despite regular bronchodilator treatment with a long acting beta 2 agonist (LABA); OR
- Patient must have been stabilised on a combination of a LAMA and a LABA.

umeclidinium 62.5 microgram/actuation + vilanterol 25 microgram/actuation powder for inhalation, 30 actuations

14358Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±2	5	..	*170.97	31.60	Anoro Ellipta 62.5/25 [GK]

▪ **VENLAFAXINE**

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.

Restricted benefit

Major depressive disorders

Clinical criteria:

- The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

venlafaxine 75 mg modified release capsule, 28

14472Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*20.99	22.44	^a APO-Venlafaxine XR [TX]	^a Elaxine SR 75 [RW]
						^a Enlafax-XR [AF]	^a Sandoz Venlafaxine XR [HX]
						^a Venlafaxine generichealth XR [GQ]	^a VENLAFAXINE XR-WGR [WG]
			^b 4.30	*25.29	22.44	^a Efexor-XR [UJ]	

venlafaxine 150 mg modified release capsule, 28

14402B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	2	..	*22.07	23.52	^a APO-Venlafaxine XR [TX]	^a Elaxine SR 150 [RW]
						^a Enlafax-XR [AF]	^a Sandoz Venlafaxine XR [HX]
						^a Venlafaxine generichealth XR [GQ]	^a VENLAFAXINE XR-WGR [WG]
			^b 4.14	*26.21	23.52	^a Efexor-XR [UJ]	

Highly Specialised Drugs Program (Private Hospital)

▪ GANCICLOVIR

Authority required (STREAMLINED)

15784

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority required (STREAMLINED)

15782

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

ganciclovir 500 mg injection, 5 vials

6136Y	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*250.13	^a Cymevene [PB]	^a GANCICLOVIR SXP [XC]

▪ VALGANCICLOVIR

Authority required (STREAMLINED)

15784

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority required (STREAMLINED)

15782

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

valganciclovir 50 mg/mL powder for oral liquid, 100 mL

9675F	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	11	5	..	*#4397.97	Valcyte [PB]

valganciclovir 450 mg tablet, 60

6357N	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*503.93	^a Valganciclovir Sandoz [SZ]	^a Valganciclovir Viatris [AL]

Highly Specialised Drugs Program (Public Hospital)

▪ GANCICLOVIR

Authority required (STREAMLINED)

15800

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority required (STREAMLINED)

15814

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

ganciclovir 500 mg injection, 5 vials

5749N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*232.18	^a Cymevene [PB]	^a GANCICLOVIR SXP [XC]

▪ VALGANCICLOVIR

Authority required (STREAMLINED)

15800

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority required (STREAMLINED)

15814

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

valganciclovir 50 mg/mL powder for oral liquid, 100 mL

9655E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	11	5	..	*4346.10	Valcyte [PB]

valganciclovir 450 mg tablet, 60

9569P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*476.22	^a Valganciclovir Sandoz [SZ]	^a Valganciclovir Viatris [AL]

Repatriation Pharmaceutical Benefits Scheme

▪ BISACODYL

Restricted benefit

The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.

bisacodyl 10 mg suppository, 10

14567Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	5	..	*38.73	7.70	^a Petrus Bisacodyl Suppositories [PP]
			..	*41.31	7.70	^a Dulcolax [VZ]

bisacodyl 10 mg suppository, 12

14572Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	6	4	..	*36.03	7.70	Petrus Bisacodyl Suppositories [PP]