



**Australian Government**

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**Department of Health**

**SCHEDULE OF PHARMACEUTICAL  
BENEFITS**

**SUMMARY OF CHANGES**

**EFFECTIVE 1 January 2014**

## PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 January 2014. The Schedule is updated on the first day of each month and is available on the Internet at [www.pbs.gov.au](http://www.pbs.gov.au).

### Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 January 2014 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.63
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.67
	Allowable additional patient charge*	\$4.19
Additional Fees (for safety net prices):	Ready-prepared	\$1.13
	Extemporaneously-prepared	\$1.48
Patient Co-payments:	General	\$36.90
	Concessional	\$6.00
Safety Net Thresholds:	General	\$1421.20
	Concessional	\$360.00
Safety Net Card Issue Fee:		\$9.26

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

## SUMMARY OF CHANGES

### Additions

#### Addition – Item

10016E	<b>Benztropine</b> , benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials ( <i>Benztropine Omega</i> ) ( <b>Prescriber Bag</b> )
10013B	<b>Benztropine</b> , benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials ( <i>Benztropine Omega</i> )
10027R	<b>Benztropine</b> , benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials ( <i>Benztropine Omega</i> )
10024N	<b>Budesonide + Eformoterol</b> , budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations ( <i>Symbicort Rapihaler 50/3</i> )
10015D	<b>Budesonide + Eformoterol</b> , budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations ( <i>Symbicort Rapihaler 100/3</i> )
10018G	<b>Budesonide + Eformoterol</b> , budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: pressurised, 120 actuations ( <i>Symbicort Rapihaler 200/6</i> )
10026Q	<b>Cyclophosphamide</b> , cyclophosphamide 50 mg tablet, 50 ( <i>Endoxan</i> )
10022L	<b>Erlotinib</b> , erlotinib 25 mg tablet, 30 ( <i>Tarceva</i> )
10028T	<b>Erlotinib</b> , erlotinib 25 mg tablet, 30 ( <i>Tarceva</i> )
10020J	<b>Erlotinib</b> , erlotinib 100 mg tablet, 30 ( <i>Tarceva</i> )
10019H	<b>Erlotinib</b> , erlotinib 100 mg tablet, 30 ( <i>Tarceva</i> )
10014C	<b>Erlotinib</b> , erlotinib 150 mg tablet, 30 ( <i>Tarceva</i> )
10025P	<b>Erlotinib</b> , erlotinib 150 mg tablet, 30 ( <i>Tarceva</i> )

#### Addition – Brand

3058Y	<i>Cephalex 250, CR</i> – <b>Cephalexin</b> , cephalexin 250 mg capsule, 20
2655R	<i>Cephalex 250, CR</i> – <b>Cephalexin</b> , cephalexin 250 mg capsule, 20
3317N	<i>Cephalex 250, CR</i> – <b>Cephalexin</b> , cephalexin 250 mg capsule, 20
1368B	<i>APO-Enalapril, TX</i> – <b>Enalapril</b> , enalapril maleate 10 mg tablet, 30
1369C	<i>APO-Enalapril, TX</i> – <b>Enalapril</b> , enalapril maleate 20 mg tablet, 30
1370D	<i>APO-Enalapril, TX</i> – <b>Enalapril</b> , enalapril maleate 5 mg tablet, 30
1182F	<i>APO-Fosinopril, TX</i> – <b>Fosinopril</b> , fosinopril sodium 10 mg tablet, 30
1183G	<i>APO-Fosinopril, TX</i> – <b>Fosinopril</b> , fosinopril sodium 20 mg tablet, 30
8401E	<i>Fosinopril/HCTZ Actavis 20/12.5, UA</i> – <b>Fosinopril + Hydrochlorothiazide</b> , fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30
8374R	<i>Leflunomide GH, GQ</i> – <b>Leflunomide</b> , leflunomide 10 mg tablet, 30
8375T	<i>Leflunomide GH, GQ</i> – <b>Leflunomide</b> , leflunomide 20 mg tablet, 30
8612G	<i>APO-MACROGOL plus ELECTROLYTES, TX</i> – <b>Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate</b> , macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets
5389P	<i>APO-MACROGOL plus ELECTROLYTES, TX</i> – <b>Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate</b> , macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets ( <b>Palliative Care</b> )
5390Q	<i>APO-MACROGOL plus ELECTROLYTES, TX</i> – <b>Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate</b> , macrogol-3350 13.12 g + sodium chloride 350.7 mg + potassium chloride 46.6 mg (0.63 mmol potassium) + sodium bicarbonate 178.5 mg solution, 30 sachets ( <b>Palliative Care</b> )
8185T	<i>Olanzapine GH, GQ</i> – <b>Olanzapine</b> , olanzapine 5 mg tablet, 28
8187X	<i>Olanzapine GH, GQ</i> – <b>Olanzapine</b> , olanzapine 10 mg tablet, 28
2236Q	<i>APO-Sertraline, TX</i> – <b>Sertraline</b> , sertraline 50 mg tablet, 30
2237R	<i>APO-Sertraline, TX</i> – <b>Sertraline</b> , sertraline 100 mg tablet, 30

### Deletions

#### Deletion – Item

8808N	<b>Aprepitant</b> , aprepitant 125 mg capsule [1 capsule] (&) aprepitant 80 mg capsule [2 capsules], 3 ( <i>Emend</i> )
1446D	<b>Bromocriptine</b> , bromocriptine 5 mg capsule, 60 ( <i>Kripton 5</i> )
2867X	<b>Budesonide + Eformoterol</b> , budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 2 x 120 actuations ( <i>Symbicort Rapihaler 50/3</i> )
2938P	<b>Budesonide + Eformoterol</b> , budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 2 x 120 actuations ( <i>Symbicort Rapihaler 100/3</i> )
2866W	<b>Budesonide + Eformoterol</b> , budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: pressurised, 2 x 120 actuations ( <i>Symbicort Rapihaler 200/6</i> )

- 8373Q **Leflunomide**, leflunomide 100 mg tablet [3 tablets] (&) leflunomide 20 mg tablet [30 tablets], 33 (*Arava*)  
 9026C **Miconazole**, miconazole nitrate 2% (20 mg/g) cream, 15 g (*Daktarin*)  
 9030G **Miconazole**, miconazole nitrate 2% (20 mg/mL) lotion, 30 g (*Daktarin*)  
 2349P **Milk Powder Lactose Free Formula Predigested**, milk powder lactose free formula predigested oral liquid: powder for, 900 g (*Karicare Aptamil De-Lact*)  
 2350Q **Milk Powder Lactose Free Formula Predigested**, milk powder lactose free formula predigested oral liquid: powder for, 900 g (*Karicare Aptamil De-Lact*)  
 8208B **Pamidronate Disodium**, pamidronate disodium 15 mg injection [4 x 15 mg vials] (&) inert substance diluent [4 x 5 mL ampoules], 1 pack (*Aredia 15 mg*)  
 8629E **Triglycerides Medium Chain Formula**, triglycerides medium chain formula oral liquid: powder for, 420 g (*Caprilon*)

## Deletion – Brand

- 8511Y *Adronat, AF* – **Alendronate**, alendronate 70 mg tablet, 4  
 3317N *Pharmacor Cephalexin 250, CR* – **Cephalexin**, cephalexin 250 mg capsule, 20  
 3058Y *Pharmacor Cephalexin 250, CR* – **Cephalexin**, cephalexin 250 mg capsule, 20  
 2655R *Pharmacor Cephalexin 250, CR* – **Cephalexin**, cephalexin 250 mg capsule, 20  
 9474P *B. Braun Australia Pty Ltd, BR* – **Glucose**, glucose 5% (12.5 g/250 mL) injection, 1 x 250 mL bag  
 9444C *B. Braun Australia Pty Ltd, BR* – **Glucose**, glucose 5% (25 g/500 mL) injection, 1 x 500 mL bag  
 5005K *B. Braun Australia Pty Ltd, BR* – **Glucose**, glucose 5% (25 g/500 mL) injection, 1 x 500 mL bag  
 2245E *B. Braun Australia Pty Ltd, BR* – **Glucose**, glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag  
 5106R *B. Braun Australia Pty Ltd, BR* – **Glucose**, glucose 5% (50 g/1000 mL) injection, 1 x 1000 mL bag  
 2546B *Aldiq, QA* – **Imiquimod**, imiquimod 5% (12.5 mg/250 mg) cream, 12 x 250 mg sachets  
 9416N *B. Braun Australia Pty Ltd, BR* – **Lactate + Sodium Chloride + Potassium Chloride + Calcium Chloride Dihydrate**, lactate sodium 0.322% (1.61 g/500 mL) + sodium chloride 0.6% (3 g/500 mL) + potassium chloride 0.04% (200 mg/500 mL) + calcium chloride dihydrate 0.027% (135 mg/500 mL) injection, 1 x 500 mL bag  
 2286H *B. Braun Australia Pty Ltd, BR* – **Lactate + Sodium Chloride + Potassium Chloride + Calcium Chloride Dihydrate**, lactate sodium 0.322% (3.22 g/1000 mL) + sodium chloride 0.6% (6 g/1000 mL) + potassium chloride 0.04% (400 mg/1000 mL) + calcium chloride dihydrate 0.027% (270 mg/1000 mL) injection, 1 x 1000 mL bag  
 3064G *Duphalac, AB* – **Lactulose**, LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1  
 5387M *Duphalac, AB* – **Lactulose**, LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1 (**Palliative Care**)  
 5388N *Duphalac, AB* – **Lactulose**, LACTULOSE Mixture 3.34 g per 5 mL, 500 mL, 1 (**Palliative Care**)  
 3065H *Barbloc 15, AF* – **Pindolol**, pindolol 15 mg tablet, 50  
 9473N *B. Braun Australia Pty Ltd, BR* – **Sodium Chloride**, sodium chloride 0.9% (2.25 g/250 mL) injection, 1 x 250 mL bag  
 5021G *B. Braun Australia Pty Ltd, BR* – **Sodium Chloride**, sodium chloride 0.9% (4.5 g/500 mL) injection, 1 x 500 mL bag  
 9392H *B. Braun Australia Pty Ltd, BR* – **Sodium Chloride**, sodium chloride 0.9% (4.5 g/500 mL) injection, 1 x 500 mL bag  
 2264E *B. Braun Australia Pty Ltd, BR* – **Sodium Chloride**, sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag  
 5212H *B. Braun Australia Pty Ltd, BR* – **Sodium Chloride**, sodium chloride 0.9% (9 g/1000 mL) injection, 1 x 1000 mL bag

## Deletion – Equivalence Indicator

- 9474P *Glucose 5% Freeflex, PK* – **Glucose**, glucose 5% (12.5 g/250 mL) injection, 1 x 250 mL bag  
 9444C *Fresenius Kabi Australia Pty Limited, PK* – **Glucose**, glucose 5% (25 g/500 mL) injection, 1 x 500 mL bag  
 5005K *Fresenius Kabi Australia Pty Limited, PK* – **Glucose**, glucose 5% (25 g/500 mL) injection, 1 x 500 mL bag  
 8461H *Pamisol, HH* – **Pamidronate Disodium**, pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial  
 3065H *Visken 15, NV* – **Pindolol**, pindolol 15 mg tablet, 50  
 9473N *Sodium Chloride 0.9% Freeflex, PK* – **Sodium Chloride**, sodium chloride 0.9% (2.25 g/250 mL) injection, 1 x 250 mL bag  
 5021G *Fresenius Kabi Australia Pty Limited, PK* – **Sodium Chloride**, sodium chloride 0.9% (4.5 g/500 mL) injection, 1 x 500 mL bag  
 9392H *Fresenius Kabi Australia Pty Limited, PK* – **Sodium Chloride**, sodium chloride 0.9% (4.5 g/500 mL) injection, 1 x 500 mL bag  
 9416N *Fresenius Kabi Australia Pty Limited, PK* – **Lactate + Sodium Chloride + Potassium Chloride + Calcium Chloride Dihydrate**, lactate sodium 0.322% (1.61 g/500 mL) + sodium chloride 0.6% (3 g/500 mL) + potassium chloride 0.04% (200 mg/500 mL) + calcium chloride dihydrate 0.027% (135 mg/500 mL) injection, 1 x 500 mL bag

## Alterations

### Alteration – Number of Repeats

- |       |   |                  |
|-------|---|------------------|
| 8456C | <b>Quetiapine</b> , quetiapine 25 mg tablet, 60 ( <i>APO-Quetiapine, Chem mart Quetiapine, Delucon 25, Pharmacy Choice Quetiapine, Quetiaccord, Quetiapine Actavis 25, Quetiapine-DRLA, Quetiapine-GA, Quetiapine GH 25, Quetiapine RBX, Quetiapine Sandoz, Quipine, Sequase, Seronia 25, Seroquel, Syquet, Terry White Chemists Quetiapine</i> ) | From: 5<br>To: 0 |
|-------|---|------------------|

### Alteration – Restriction

Please note that all Authority Required (STREAMLINED) items which have had alterations made to the restriction will have new authority codes.

- 1180D **Amino Acid Synthetic Formula**, amino acid synthetic formula oral liquid: powder for, 400 g (*Neocate Advance Vanilla*)

- 8574G **Amino Acid Synthetic Formula**, amino acid synthetic formula oral liquid: powder for, 400 g (*EleCare*)
- 1192R **Amino Acid Synthetic Formula**, amino acid synthetic formula oral liquid: powder for, 400 g (*Neocate Advance Vanilla*)
- 8575H **Amino Acid Synthetic Formula**, amino acid synthetic formula oral liquid: powder for, 400 g (*EleCare*)
- 1521C **Amino Acid Synthetic Formula**, amino acid synthetic formula oral liquid: powder for, 400 g (*Neocate Advance Vanilla*)
- 2250K **Amino Acid Synthetic Formula**, amino acid synthetic formula oral liquid: powder for, 400 g (*EleCare*)
- 8754R **Amino Acid Synthetic Formula**, amino acid synthetic formula oral liquid: powder for, 400 g (*Neocate Advance*)
- 8755T **Amino Acid Synthetic Formula**, amino acid synthetic formula oral liquid: powder for, 400 g (*Neocate Advance*)
- 2246F **Amino Acid Synthetic Formula Supplemented With Long Chain Polyunsaturated Fatty Acids**, amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g (*Neocate LCP*)
- 9339M **Amino Acid Synthetic Formula Supplemented With Long Chain Polyunsaturated Fatty Acids**, amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g (*EleCare LCP*)
- 2560R **Amino Acid Synthetic Formula Supplemented With Long Chain Polyunsaturated Fatty Acids**, amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g (*Neocate LCP*)
- 9340N **Amino Acid Synthetic Formula Supplemented With Long Chain Polyunsaturated Fatty Acids**, amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g (*EleCare LCP*)
- 5466Q **Amino Acid Synthetic Formula Supplemented With Long Chain Polyunsaturated Fatty Acids And Medium Chain Triglycerides**, amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g (*Neocate Gold*)
- 5467R **Amino Acid Synthetic Formula Supplemented With Long Chain Polyunsaturated Fatty Acids And Medium Chain Triglycerides**, amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g (*Neocate Gold*)
- 1545H **Amino Acid Synthetic Formula Supplemented With Long Chain Polyunsaturated Fatty Acids And Medium Chain Triglycerides**, amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g (*Neocate Gold*)
- 9375K **Amlodipine + Valsartan**, amlodipine 5 mg + valsartan 80 mg tablet, 28 (*Exforge 5/80, Valsartan/Amlodipine Sandoz 80/5*)
- 9376L **Amlodipine + Valsartan**, amlodipine 5 mg + valsartan 160 mg tablet, 28 (*Exforge 5/160*)
- 9377M **Amlodipine + Valsartan**, amlodipine 10 mg + valsartan 160 mg tablet, 28 (*Exforge 10/160*)
- 5459H **Amlodipine + Valsartan**, amlodipine 5 mg + valsartan 320 mg tablet, 28 (*Exforge 5/320*)
- 5460J **Amlodipine + Valsartan**, amlodipine 10 mg + valsartan 320 mg tablet, 28 (*Exforge 10/320*)
- 5285E **Amlodipine + Valsartan + Hydrochlorothiazide**, amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28 (*Exforge HCT 5/160/12.5, Valsartan/Amlodipine/HCT Sandoz 160/5/12.5*)
- 5286F **Amlodipine + Valsartan + Hydrochlorothiazide**, amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28 (*Exforge HCT 5/160/25*)
- 5287G **Amlodipine + Valsartan + Hydrochlorothiazide**, amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28 (*Exforge HCT 10/160/12.5*)
- 5288H **Amlodipine + Valsartan + Hydrochlorothiazide**, amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28 (*Exforge HCT 10/160/25*)
- 5289J **Amlodipine + Valsartan + Hydrochlorothiazide**, amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28 (*Exforge HCT 10/320/25*)
- 8796Y **Budesonide + Eformoterol**, budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 120 actuations (*Symbicort Turbuhaler 100/6*)
- 8625Y **Budesonide + Eformoterol**, budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 120 actuations (*Symbicort Turbuhaler 200/6*)
- 8750M **Budesonide + Eformoterol**, budesonide 400 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 120 actuations (*Symbicort Turbuhaler 400/12*)
- 8504N **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30 (*Adesan HCT 16/12.5, APO-Candesartan HCTZ 16/12.5, Atacand Plus 16/12.5, Candesartan/HCT Sandoz, Candesartan Combi Aspen 16/12.5, Candesartan HCT GH 16/12.5, Candesartan HCTZ-GA 16/12.5, Candesartan HCTZ RBX 16/12.5, Pharmacor Candesartan HCT 16/12.5*)
- 9314F **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30 (*APO-Candesartan HCTZ 32/12.5, Atacand Plus 32/12.5, Candesartan/HCT Sandoz, Candesartan Combi Aspen 32/12.5, Candesartan HCT GH 32/12.5, Candesartan HCTZ-GA 32/12.5, Candesartan HCTZ RBX 32/12.5, Pharmacor Candesartan HCT 32/12.5*)
- 9315G **Candesartan + Hydrochlorothiazide**, candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30 (*APO-Candesartan HCTZ 32/25, Atacand Plus 32/25, Candesartan/HCT Sandoz, Candesartan Combi Aspen 32/25, Candesartan HCT GH 32/25, Candesartan HCTZ-GA 32/25, Candesartan HCTZ RBX 32/25, Pharmacor Candesartan HCT 32/25*)
- 2896K **Dimethyl Fumarate**, dimethyl fumarate 120 mg capsule, 14 (*Tecfidera*)
- 2943X **Dimethyl Fumarate**, dimethyl fumarate 120 mg capsule, 14 (*Tecfidera*)
- 2966D **Dimethyl Fumarate**, dimethyl fumarate 240 mg capsule, 56 (*Tecfidera*)
- 8477E **Enalapril + Hydrochlorothiazide**, enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30 (*Enalapril/HCT Sandoz, Renitec Plus 20/6*)
- 8624X **Eprosartan + Hydrochlorothiazide**, eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28 (*Teveten Plus 600/12.5*)
- 9166K **Erlotinib**, erlotinib 25 mg tablet, 30 (*Tarceva*)
- 9167L **Erlotinib**, erlotinib 100 mg tablet, 30 (*Tarceva*)
- 9168M **Erlotinib**, erlotinib 150 mg tablet, 30 (*Tarceva*)
- 3423E **Exenatide**, exenatide 5 microgram/20 microlitre injection, 60 unit doses (*Byetta 5 microgram*)
- 3424F **Exenatide**, exenatide 10 microgram/40 microlitre injection, 60 unit doses (*Byetta 10 microgram*)
- 2827T **Fluticasone + Eformoterol**, fluticasone propionate 50 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations (*flutiform 50/5*)

- 10007Q **Fluticasone + Eformoterol**, fluticasone propionate 125 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations (*flutiform 125/5*)
- 10008R **Fluticasone + Eformoterol**, fluticasone propionate 250 microgram/actuation + eformoterol fumarate dihydrate 10 microgram/actuation inhalation: pressurised, 120 actuations (*flutiform 250/10*)
- 8517G **Fluticasone + Salmeterol**, fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations (*Seretide MDI 50/25*)
- 8518H **Fluticasone + Salmeterol**, fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations (*Seretide MDI 125/25*)
- 8430Q **Fluticasone + Salmeterol**, fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations (*Seretide Accuhaler 100/50*)
- 8431R **Fluticasone + Salmeterol**, fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations (*Seretide Accuhaler 250/50*)
- 8519J **Fluticasone + Salmeterol**, fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations (*Seretide MDI 250/25*)
- 8432T **Fluticasone + Salmeterol**, fluticasone propionate 500 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations (*Seretide Accuhaler 500/50*)
- 8400D **Fosinopril + Hydrochlorothiazide**, fosinopril sodium 10 mg + hydrochlorothiazide 12.5 mg tablet, 30 (*APO-Fosinopril HCTZ 10/12.5, Fosinopril/HCTZ-GA 10/12.5, Hyforil, Monoplus 10/12.5*)
- 8401E **Fosinopril + Hydrochlorothiazide**, fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30 (*APO-Fosinopril HCTZ 20/12.5, Fosetic 20/12.5, Fosinopril/HCT Actavis 20/12.5, Fosinopril/HCTZ-GA 20/12.5, Hyforil, Monoplus 20/12.5*)
- 8769M **Gefitinib**, gefitinib 250 mg tablet, 30 (*Iressa*)
- 8404H **Irbesartan + Hydrochlorothiazide**, irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30 (*Abisart HCT 150/12.5, APO-Irbesartan HCTZ, Avapro HCT 150/12.5, Chem mart Irbesartan HCTZ, Irbesartan/HCT Sandoz, Irbesartan/HCTZ RBX 150/12.5, Irbesartan HCT Winthrop 150/12.5, Irbesartan HCTZ-GA 150/12.5, Irbesatzide GH 150/12.5, Karvezide 150/12.5, KSART HCT 150/12.5, Terry White Chemists Irbesartan HCTZ*)
- 8405J **Irbesartan + Hydrochlorothiazide**, irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30 (*Abisart HCT 300/12.5, APO-Irbesartan HCTZ, Avapro HCT 300/12.5, Chem mart Irbesartan HCTZ, Irbesartan/HCT Sandoz, Irbesartan/HCTZ RBX 300/12.5, Irbesartan HCT Winthrop 300/12.5, Irbesartan HCTZ-GA 300/12.5, Irbesatzide GH 300/12.5, Karvezide 300/12.5, KSART HCT 300/12.5, Terry White Chemists Irbesartan HCTZ*)
- 2136K **Irbesartan + Hydrochlorothiazide**, irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30 (*Abisart HCT 300/25, APO-Irbesartan HCTZ, Avapro HCT 300/25, Chem mart Irbesartan HCTZ, Irbesartan/HCT Sandoz, Irbesartan/HCTZ RBX 300/25, Irbesartan HCT Winthrop 300/25, Irbesartan HCTZ-GA 300/25, Irbesatzide GH 300/25, Karvezide 300/25, KSART HCT 300/25, Terry White Chemists Irbesartan HCTZ*)
- 9144G **Lercanidipine + Enalapril**, lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28 (*Zan-Extra 10/10*)
- 9145H **Lercanidipine + Enalapril**, lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28 (*Zan-Extra 10/20*)
- 5292M **Olmesartan Medoxomil + Amlodipine**, olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30 (*Sevikar 20/5*)
- 5294P **Olmesartan Medoxomil + Amlodipine**, olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30 (*Sevikar 40/10*)
- 5293N **Olmesartan Medoxomil + Amlodipine**, olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30 (*Sevikar 40/5*)
- 2161R **Olmesartan Medoxomil + Hydrochlorothiazide**, olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30 (*Olmotec Plus*)
- 2166B **Olmesartan Medoxomil + Hydrochlorothiazide**, olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30 (*Olmotec Plus*)
- 2170F **Olmesartan Medoxomil + Hydrochlorothiazide**, olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30 (*Olmotec Plus*)
- 9346X **Perindopril + Amlodipine**, perindopril arginine 5 mg + amlodipine 5 mg tablet, 30 (*Coveram 5/5, Reaptan 5/5*)
- 9347Y **Perindopril + Amlodipine**, perindopril arginine 5 mg + amlodipine 10 mg tablet, 30 (*Coveram 5/10, Reaptan 5/10*)
- 9348B **Perindopril + Amlodipine**, perindopril arginine 10 mg + amlodipine 5 mg tablet, 30 (*Coveram 10/5, Reaptan 10/5*)
- 9349C **Perindopril + Amlodipine**, perindopril arginine 10 mg + amlodipine 10 mg tablet, 30 (*Coveram 10/10, Reaptan 10/10*)
- 2845R **Perindopril + Indapamide**, perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30 (*Coversyl Plus 5mg/1.25mg, Prexum Combi 5/1.25*)
- 8449Q **Perindopril + Indapamide**, perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30 (*Chem mart Perindopril/Indapamide 4/1.25, GenRx Perindopril/Indapamide 4/1.25, Idaprex Combi 4/1.25, Indosyl Combi 4/1.25, Perindo Combi 4/1.25, Perindopril/Indapamide GH 4/1.25, Terry White Chemists Perindopril/Indapamide 4/1.25*)
- 8694N **Pioglitazone**, pioglitazone 15 mg tablet, 28 (*Acpio 15, Actos, APOTEX-Pioglitazone, Chem mart Pioglitazone, Pharmacor Pioglitazone 15, Pioglitazone-GA, Pioglitazone generichealth 15, Pioglitazone Sandoz, Pizaccord, Prioten 15, Terry White Chemists Pioglitazone, Vexazone*)
- 8695P **Pioglitazone**, pioglitazone 30 mg tablet, 28 (*Acpio 30, Actos, APOTEX-Pioglitazone, Chem mart Pioglitazone, Pharmacor Pioglitazone 30, Pioglitazone-GA, Pioglitazone generichealth 30, Pioglitazone Sandoz, Pizaccord, Prioten 30, Terry White Chemists Pioglitazone, Vexazone*)
- 8696Q **Pioglitazone**, pioglitazone 45 mg tablet, 28 (*Acpio 45, Actos, APOTEX-Pioglitazone, Chem mart Pioglitazone, Pharmacor Pioglitazone 45, Pioglitazone-GA, Pioglitazone generichealth 45, Pioglitazone Sandoz, Pizaccord, Prioten 45, Terry White Chemists Pioglitazone, Vexazone*)
- 2676W **Protein Hydrolysate Formula With Medium Chain Triglycerides**, protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g (*Alfaré*)
- 8259Q **Protein Hydrolysate Formula With Medium Chain Triglycerides**, protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g (*Karicare Aptamil Pepti-Junior Gold*)
- 8456C **Quetiapine**, quetiapine 25 mg tablet, 60 (*APO-Quetiapine, Chem mart Quetiapine, Delucon 25, Pharmacy Choice Quetiapine,*

*Quetiaccord, Quetiapine Actavis 25, Quetiapine-DRLA, Quetiapine-GA, Quetiapine GH 25, Quetiapine RBX, Quetiapine Sandoz, Quipine, Sequase, Seronia 25, Seroquel, Syquet, Terry White Chemists Quetiapine)*

8589C	<b>Quinapril + Hydrochlorothiazide</b> , quinapril 10 mg + hydrochlorothiazide 12.5 mg tablet, 30 ( <i>Accuretic 10/12.5mg</i> )
8590D	<b>Quinapril + Hydrochlorothiazide</b> , quinapril 20 mg + hydrochlorothiazide 12.5 mg tablet, 30 ( <i>Accuretic 20/12.5mg</i> )
2626F	<b>Ramipril + Felodipine</b> , ramipril 2.5 mg + felodipine 2.5 mg tablet: modified release, 30 tablets ( <i>Triasyn 2.5/2.5</i> )
2629J	<b>Ramipril + Felodipine</b> , ramipril 5 mg + felodipine 5 mg tablet: modified release, 30 tablets ( <i>Triasyn 5.0/5.0</i> )
8689H	<b>Rosiglitazone</b> , rosiglitazone 4 mg tablet, 28 ( <i>Avandia</i> )
8690J	<b>Rosiglitazone</b> , rosiglitazone 8 mg tablet, 28 ( <i>Avandia</i> )
9060W	<b>Rosiglitazone + Metformin</b> , rosiglitazone 2 mg + metformin hydrochloride 1 g tablet, 56 ( <i>Avandamet</i> )
9059T	<b>Rosiglitazone + Metformin</b> , rosiglitazone 2 mg + metformin hydrochloride 500 mg tablet, 56 ( <i>Avandamet</i> )
9062Y	<b>Rosiglitazone + Metformin</b> , rosiglitazone 4 mg + metformin hydrochloride 1 g tablet, 56 ( <i>Avandamet</i> )
9061X	<b>Rosiglitazone + Metformin</b> , rosiglitazone 4 mg + metformin hydrochloride 500 mg tablet, 56 ( <i>Avandamet</i> )
8978M	<b>Telmisartan + Amlodipine</b> , telmisartan 40 mg + amlodipine 5 mg tablet, 28 ( <i>Twynsta</i> )
8979N	<b>Telmisartan + Amlodipine</b> , telmisartan 40 mg + amlodipine 10 mg tablet, 28 ( <i>Twynsta</i> )
8980P	<b>Telmisartan + Amlodipine</b> , telmisartan 80 mg + amlodipine 5 mg tablet, 28 ( <i>Twynsta</i> )
8981Q	<b>Telmisartan + Amlodipine</b> , telmisartan 80 mg + amlodipine 10 mg tablet, 28 ( <i>Twynsta</i> )
8622T	<b>Telmisartan + Hydrochlorothiazide</b> , telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28 ( <i>Micardis Plus 40/12.5 mg, Pritor Plus 40/12.5 mg</i> )
8623W	<b>Telmisartan + Hydrochlorothiazide</b> , telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28 ( <i>Micardis Plus 80/12.5 mg, Pritor Plus 80/12.5 mg</i> )
9381R	<b>Telmisartan + Hydrochlorothiazide</b> , telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28 ( <i>Micardis Plus 80/25 mg, Pritor Plus 80/25 mg</i> )
9411H	<b>Teriparatide</b> , teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge ( <i>Forteo</i> )
9387C	<b>Trandolapril + Verapamil</b> , trandolapril 2 mg + verapamil hydrochloride 180 mg tablet: modified release, 28 tablets ( <i>Tarka 2/180</i> )
2857J	<b>Trandolapril + Verapamil</b> , trandolapril 4 mg + verapamil hydrochloride 240 mg tablet: modified release, 28 tablets ( <i>Tarka 4/240</i> )
9372G	<b>Valsartan + Hydrochlorothiazide</b> , valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28 ( <i>Co-Diovan 80/12.5</i> )
9373H	<b>Valsartan + Hydrochlorothiazide</b> , valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28 ( <i>Co-Diovan 160/12.5</i> )
9374J	<b>Valsartan + Hydrochlorothiazide</b> , valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28 ( <i>Co-Diovan 160/25</i> )
9481B	<b>Valsartan + Hydrochlorothiazide</b> , valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28 ( <i>Co-Diovan 320/12.5</i> )
9482C	<b>Valsartan + Hydrochlorothiazide</b> , valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28 ( <i>Co-Diovan 320/25</i> )

### Alteration – Authority required to Authority required (STREAMLINED)

Please note that alterations have also been made to these restrictions.

5500L	<b>Apixaban</b> , apixaban 2.5 mg tablet, 20 ( <i>Eliquis</i> )
5054B	<b>Apixaban</b> , apixaban 2.5 mg tablet, 30 ( <i>Eliquis</i> )
5061J	<b>Apixaban</b> , apixaban 2.5 mg tablet, 60 ( <i>Eliquis</i> )
9321N	<b>Dabigatran</b> , dabigatran etexilate 110 mg capsule, 60 ( <i>Pradaxa</i> )
9320M	<b>Dabigatran</b> , dabigatran etexilate 75 mg capsule, 60 ( <i>Pradaxa</i> )
9319L	<b>Dabigatran</b> , dabigatran etexilate 110 mg capsule, 10 ( <i>Pradaxa</i> )
9318K	<b>Dabigatran</b> , dabigatran etexilate 75 mg capsule, 10 ( <i>Pradaxa</i> )
9323Q	<b>Dabigatran</b> , dabigatran etexilate 110 mg capsule, 10 ( <i>Pradaxa</i> )
9322P	<b>Dabigatran</b> , dabigatran etexilate 75 mg capsule, 10 ( <i>Pradaxa</i> )
9467G	<b>Rivaroxaban</b> , RIVAROXABAN Tablet 10 mg, 30 ( <i>Xarelto</i> )
9465E	<b>Rivaroxaban</b> , rivaroxaban 10 mg tablet, 10 ( <i>Xarelto</i> )
9468H	<b>Rivaroxaban</b> , rivaroxaban 10 mg tablet, 10 ( <i>Xarelto</i> )
9466F	<b>Rivaroxaban</b> , rivaroxaban 10 mg tablet, 15 ( <i>Xarelto</i> )
9469J	<b>Rivaroxaban</b> , rivaroxaban 10 mg tablet, 15 ( <i>Xarelto</i> )

### Alteration – Manufacturer's Code

		From:	To:
2502Q	<i>Calciprox, ER</i> – <b>Calcitriol</b> , calcitriol 0.25 microgram capsule, 100	GN	ER
2412Y	<i>Frusax, ER</i> – <b>Frusemide</b> , frusemide 40 mg tablet, 100	GN	ER
8007K	<i>Pantron, ER</i> – <b>Pantoprazole</b> , pantoprazole 40 mg tablet: enteric, 30	GN	ER
8008L	<i>Pantron, ER</i> – <b>Pantoprazole</b> , pantoprazole 40 mg tablet: enteric, 30	GN	ER

## Advance Notices

### Advance Notices – Deletion of Item

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

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

(Firmagon 80mg)

8545R **Amino Acid Formula With Vitamins And Minerals Without Phenylalanine**, amino acid formula with vitamins and minerals without phenylalanine oral liquid: powder for, 400 g (*Phenex-2*)

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

1252X **Terbutaline**, terbutaline sulfate 500 microgram/actuation inhalation: powder for, 200 actuations (*Bricanyl Turbuhaler*)

## Advance Notices – Deletion of Brand

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

2130D *Xanax, PF* – **Alprazolam**, alprazolam 250 microgram tablet, 50

2131E *Xanax, PF* – **Alprazolam**, alprazolam 500 microgram tablet, 50

2132F *Xanax, PF* – **Alprazolam**, alprazolam 1 mg tablet, 50

8118G *Xanax Tri-Score, PF* – **Alprazolam**, alprazolam 2 mg tablet, 50

## SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

### Deletions

#### Deletion – Item

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

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

5701C **Pamidronate Disodium**, pamidronate disodium 15 mg injection [4 x 15 mg vials] (&) inert substance diluent [4 x 5 mL ampoules], 1 pack (*Aredia 15 mg*) (**Public**)

6290C **Pamidronate Disodium**, pamidronate disodium 15 mg injection [4 x 15 mg vials] (&) inert substance diluent [4 x 5 mL ampoules], 1 pack (*Aredia 15 mg*) (**Private**)

#### Deletion – Equivalence Indicator

5667G *Pamisol, HH* – **Pamidronate Disodium**, pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial (**Public**)

6286W *Pamisol, HH* – **Pamidronate Disodium**, pamidronate disodium 15 mg/5 mL injection, 1 x 5 mL vial (**Private**)

### Alterations

#### Alteration – Restriction & Note Addition

Please note that all Authority Required (STREAMLINED) items which have had alterations made to the restriction will have new authority codes.

6101D **Clozapine**, clozapine 25 mg tablet, 100 (*Clopine 25, Clozaril 25*)(**Private**)

5628F **Clozapine**, clozapine 25 mg tablet, 100 (*Clopine 25, Clozaril 25*)(**Public**)

6417R **Clozapine**, clozapine 50 mg tablet, 100 (*Clopine 50*)(**Private**)

5626D **Clozapine**, clozapine 50 mg tablet, 100 (*Clopine 50*)(**Public**)

6102E **Clozapine**, clozapine 100 mg tablet, 100 (*Clopine 100, Clozaril 100*)(**Private**)

5629G **Clozapine**, clozapine 100 mg tablet, 100 (*Clopine 100, Clozaril 100*)(**Public**)

6418T **Clozapine**, clozapine 200 mg tablet, 100 (*Clopine 200*)(**Private**)

5627E **Clozapine**, clozapine 200 mg tablet, 100 (*Clopine 200*)(**Public**)

9632Y **Clozapine**, clozapine 50 mg/mL oral liquid, 100 mL (*Clopine Suspension*)(**Private**)

5630H **Clozapine**, clozapine 50 mg/mL oral liquid, 100 mL (*Clopine Suspension*)(**Public**)

## REPATRIATION PHARMACEUTICAL BENEFITS

### Additions

#### Addition – Item

10031Y	<b>Alprostadil</b> , alprostadil 10 microgram injection [1 x 10 microgram vial] (&) inert substance diluent [1 syringe], 1 pack ( <i>Caverject</i> )
10030X	<b>Alprostadil</b> , alprostadil 20 microgram injection [1 x 20 microgram vial] (&) inert substance diluent [1 syringe], 1 pack ( <i>Caverject</i> )
10017F	<b>Dressing Foam With Silicone</b> , dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10 ( <i>Allevyn Life 66801067</i> )
10029W	<b>Dressing Foam With Silicone</b> , dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10 ( <i>Allevyn Life 66801068</i> )
10021K	<b>Dressing Foam With Silicone</b> , dressing foam with silicone 21 cm x 21 cm dressing, 10 ( <i>Allevyn Life 66801070</i> )
10023M	<b>Dressing Foam With Silicone</b> , dressing foam with silicone 15.4 cm x 15.4 cm dressing, 10 ( <i>Allevyn Life 66801069</i> )

#### Addition – Brand

4115N	<i>APO-Azithromycin, TX</i> – <b>Azithromycin</b> , azithromycin 500 mg tablet, 3
4115N	<i>Chemmart Azithromycin, CH</i> – <b>Azithromycin</b> , azithromycin 500 mg tablet, 3
4115N	<i>Terry White Chemists Azithromycin, TW</i> – <b>Azithromycin</b> , azithromycin 500 mg tablet, 3

**PRESCRIBER BAG**

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Dispensed		Brand Name and Manufacturer
			Qty	Price for Max. \$	
<b>BENZTROPINE</b>					
10016E NP	benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials	1	287.52	Benztropine Omega	FK

## GENERAL PHARMACEUTICAL BENEFITS

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

#### **Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

#### **The Treatment criteria is:**

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

#### **AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

#### **AND the Clinical criteria is:**

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

#### **AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

#### **Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

#### **The Treatment criteria is:**

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

#### **AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

#### **AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

#### **Authority required**

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

Treatment Phase: Initial treatment for up to 6 months

#### **The Treatment criteria is:**

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

#### **AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

#### **AND the Population criteria is:**

Patient must be older than 24 months of age.

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

#### **Authority required**

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

Treatment Phase: Initial treatment for up to 6 months

#### **The Treatment criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Population criteria is:**

Patient must be up to the age of 24 months.

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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The name of the specialist and the date of birth of the patient must be included in the authority application.

**Note**

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

**Note**

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

1180D NP	amino acid synthetic formula oral liquid: powder for, 400 g	8	5	..	*361.35	36.90	Neocate Advance Vanilla	SB
8574G NP	amino acid synthetic formula oral liquid: powder for, 400 g	8	5	..	*361.35	36.90	EleCare	AB
8754R NP	amino acid synthetic formula oral liquid: powder for, 400 g	8	5	..	*361.35	36.90	Neocate Advance	SB

**AMINO ACID SYNTHETIC FORMULA**

**Authority required**

Cows' milk anaphylaxis

**The Treatment criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

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

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Clinical criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Clinical criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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The name of the specialist and the date of birth of the patient must be included in the authority application.

### **Authority required**

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

Treatment Phase: Continuing treatment

#### **The Treatment criteria is:**

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

#### **AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

#### **AND the Population criteria is:**

Patient must be older than 24 months of age.

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

### **Authority required**

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

Treatment Phase: Continuing treatment

#### **The Treatment criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

### **Authority required**

Severe intestinal malabsorption including short bowel syndrome

#### **The Clinical criteria is:**

Patient must have failed to respond to protein hydrolysate formulae; OR

Patient must have been receiving parenteral nutrition.

### **Note**

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

1192R NP	amino acid synthetic formula oral liquid: powder for, 400 g	8	5	..	*361.35	36.90	Neocate Advance Vanilla	SB
8575H NP	amino acid synthetic formula oral liquid: powder for, 400 g	8	5	..	*361.35	36.90	EleCare	AB
8755T NP	amino acid synthetic formula oral liquid: powder for, 400 g	8	5	..	*361.35	36.90	Neocate Advance	SB

### **AMINO ACID SYNTHETIC FORMULA**

#### **Authority required**

Eosinophilic oesophagitis

Treatment Phase: Initial treatment for up to 3 months

#### **The Treatment criteria is:**

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist,

#### **AND the Clinical criteria is:**

Patient must require an amino acid based formula as a component of a dietary elimination program,

#### **AND the Population criteria is:**

Patient must be 18 years of age or less.

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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Treatment with oral steroids should not be commenced during the period of initial treatment.

Eosinophilic oesophagitis is demonstrated by the following criteria:

- (i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and
- (ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and
- (iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.

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

### **Authority required**

Eosinophilic oesophagitis

Treatment Phase: Continuing treatment

#### **The Treatment criteria is:**

Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist,

#### **AND the Clinical criteria is:**

Patient must have responded to an initial course of PBS-subsidised treatment,

#### **AND the Population criteria is:**

Patient must be 18 years of age or less.

Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.

### **Note**

Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.

1521C NP	amino acid synthetic formula oral liquid: powder for, 400 g	12	5	..	*531.87	36.90	Neocate Advance Vanilla	SB
2250K NP	amino acid synthetic formula oral liquid: powder for, 400 g	12	5	..	*531.87	36.90	EleCare	AB

### **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**

#### **Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

#### **The Treatment criteria is:**

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

#### **AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

#### **AND the Clinical criteria is:**

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

#### **AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

### **Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

#### **The Treatment criteria is:**

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

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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specialist allergist, clinical immunologist or specialist paediatric gastroenterologist and hepatologist,

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

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

Treatment Phase: Initial treatment for up to 6 months

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Population criteria is:**

Patient must be older than 24 months of age.

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

**Authority required**

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

Treatment Phase: Initial treatment for up to 6 months

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Note**

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

**Note**

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

2246F NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g	8	5	..	*368.07	36.90	Neocate LCP	SB
9339M NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g	8	5	..	*368.07	36.90	EleCare LCP	AB

**AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS**

**Authority required**

Cows' milk anaphylaxis

**The Treatment criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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The name of the specialist and the date of birth of the patient must be included in the authority application.

**Authority required**

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Clinical criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Clinical criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

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

Treatment Phase: Continuing treatment

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Population criteria is:**

Patient must be older than 24 months of age.

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

**Authority required**

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

Treatment Phase: Continuing treatment

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Patient must have failed a trial of protein hydrolysate formulae (with or without medium chain triglycerides) prior to commencement with initial treatment, <b>AND the Population criteria is:</b> Patient must be up to the age of 24 months.  The name of the specialist and the date of birth of the patient must be included in the authority application.  <b>Authority required</b> Severe intestinal malabsorption including short bowel syndrome <b>The Clinical criteria is:</b> Patient must have failed to respond to protein hydrolysate formulae; OR Patient must have been receiving parenteral nutrition.  <b>Note</b> Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.							
2560R NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g	8	5	..	*368.07	36.90	Neocate LCP	SB
9340N NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g	8	5	..	*368.07	36.90	EleCare LCP	AB

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

#### **Authority required**

Cows' milk protein enteropathy

Treatment Phase: Initial treatment for up to 6 months

#### **The Treatment criteria is:**

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

#### **AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

#### **AND the Clinical criteria is:**

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

#### **AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

#### **Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Initial treatment for up to 6 months

#### **The Treatment criteria is:**

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

#### **AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

#### **AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

## GENERAL PHARMACEUTICAL BENEFITS

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

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

Treatment Phase: Initial treatment for up to 6 months

#### **The Treatment criteria is:**

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

#### **AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

#### **AND the Population criteria is:**

Patient must be older than 24 months of age.

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

### Authority required

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

Treatment Phase: Initial treatment for up to 6 months

#### **The Treatment criteria is:**

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

#### **AND the Clinical criteria is:**

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

#### **AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

### Note

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

### Note

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

5466Q NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g	8	5	..	*368.07	36.90	Neocate Gold	SB
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### **AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES**

#### Authority required

Cows' milk anaphylaxis

#### **The Treatment criteria is:**

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

#### **AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

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

### Authority required

Cows' milk protein enteropathy

Treatment Phase: Continuing treatment

#### **The Treatment criteria is:**

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

## GENERAL PHARMACEUTICAL BENEFITS

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

The condition must not be isolated infant colic or reflux,

**AND the Clinical criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

Severe cows' milk protein enteropathy with failure to thrive

Treatment Phase: Continuing treatment

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Clinical criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

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

Treatment Phase: Continuing treatment

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Population criteria is:**

Patient must be older than 24 months of age.

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

**Authority required**

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

Treatment Phase: Continuing treatment

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	<b>The Clinical criteria is:</b>						
	Patient must have failed to respond to protein hydrolysate formulae; OR						
	Patient must have been receiving parenteral nutrition.						
	<b>Note</b>						
	Authorities for increased maximum quantities, up to a maximum of 20, may be authorised.						
5467R NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g	8	5	..	*368.07	36.90	Neocate Gold SB
	<b>AMINO ACID SYNTHETIC FORMULA SUPPLEMENTED WITH LONG CHAIN POLYUNSATURATED FATTY ACIDS AND MEDIUM CHAIN TRIGLYCERIDES</b>						
	<b>Authority required</b>						
	Eosinophilic oesophagitis						
	Treatment Phase: Initial treatment for up to 3 months						
	<b>The Treatment criteria is:</b>						
	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist,						
	<b>AND the Clinical criteria is:</b>						
	Patient must require an amino acid based formula as a component of a dietary elimination program,						
	<b>AND the Population criteria is:</b>						
	Patient must be 18 years of age or less.						
	Treatment with oral steroids should not be commenced during the period of initial treatment.						
	Eosinophilic oesophagitis is demonstrated by the following criteria:						
	(i) Chronic symptoms of reflux that persisted despite a 2-month trial of a proton pump inhibitor or chronic dysphagia; and						
	(ii) A lack of demonstrable anatomic abnormality with the exception of stricture, which can be attributable to eosinophilic oesophagitis; and						
	(iii) Eosinophilic infiltration of the oesophagus, demonstrated by oesophageal biopsy specimens obtained by endoscopy and where the most densely involved oesophageal biopsy had 20 or more eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies.						
	The date of birth of the patient must be included in the authority application.						
	<b>Authority required</b>						
	Eosinophilic oesophagitis						
	Treatment Phase: Continuing treatment						
	<b>The Treatment criteria is:</b>						
	Must be treated by a clinical immunologist, suitably qualified allergist or gastroenterologist,						
	<b>AND the Clinical criteria is:</b>						
	Patient must have responded to an initial course of PBS-subsidised treatment,						
	<b>AND the Population criteria is:</b>						
	Patient must be 18 years of age or less.						
	Response to initial treatment is demonstrated by oesophageal biopsy specimens obtained by endoscopy, where the most densely involved oesophageal biopsy had 5 or less eosinophils in any single 400 x high powered field, along with normal antral and duodenal biopsies. The response criteria will not be deemed to have been met if oral steroids were commenced during initial treatment.						
	<b>Note</b>						
	Authorities for increased maximum quantities, up to a maximum of 52, may be authorised.						
1545H NP	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid:	12	5	..	*542.43	36.90	Neocate Gold SB

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	powder for, 400 g							
<b>AMLODIPINE + VALSARTAN</b>								
<b><u>Restricted benefit</u></b>								
Hypertension								
<b>The Clinical criteria is:</b>								
The treatment must not be for the initiation of anti-hypertensive therapy,								
<b>AND the Clinical criteria is:</b>								
The condition must be inadequately controlled with an angiotensin II antagonist; OR								
The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.								
9375K NP	amlodipine 5 mg + valsartan 80 mg tablet, 28	1	5	..	22.24	23.37	<sup>a</sup> Exforge 5/80	NV
							<sup>a</sup> Valsartan/Amlodipine Sandoz 80/5	NM
9376L NP	amlodipine 5 mg + valsartan 160 mg tablet, 28	1	5	..	25.31	26.44	Exforge 5/160	NV
9377M NP	amlodipine 10 mg + valsartan 160 mg tablet, 28	1	5	..	28.85	29.98	Exforge 10/160	NV
5459H NP	amlodipine 5 mg + valsartan 320 mg tablet, 28	1	5	..	29.15	30.28	Exforge 5/320	NV
5460J NP	amlodipine 10 mg + valsartan 320 mg tablet, 28	1	5	..	32.68	33.81	Exforge 10/320	NV
<b>AMLODIPINE + VALSARTAN + HYDROCHLOROTHIAZIDE</b>								
<b><u>Restricted benefit</u></b>								
Hypertension								
<b>The Clinical criteria is:</b>								
The treatment must not be for the initiation of anti-hypertensive therapy,								
<b>AND the Clinical criteria is:</b>								
The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic.								
5285E NP	amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	27.04	28.17	<sup>a</sup> Exforge HCT 5/160/12.5	NV
							<sup>a</sup> Valsartan/Amlodipine/HCT Sandoz 160/5/12.5	NM
5286F NP	amlodipine 5 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28	1	5	..	28.79	29.92	Exforge HCT 5/160/25	NV
5287G NP	amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	30.58	31.71	Exforge HCT 10/160/12.5	NV
5288H NP	amlodipine 10 mg + valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28	1	5	..	32.32	33.45	Exforge HCT 10/160/25	NV
5289J NP	amlodipine 10 mg + valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28	1	5	..	36.19	36.90	Exforge HCT 10/320/25	NV
<b>APIXABAN</b>								
<b><u>Authority required (STREAMLINED)</u></b>								
<b>4381</b>								
Prevention of venous thromboembolism								
<b>The Treatment criteria is:</b>								
Patient must be undergoing total knee replacement,								
<b>AND the Clinical criteria is:</b>								
Patient must require up to 10 days of therapy.								
<b><u>Authority required (STREAMLINED)</u></b>								
<b>4359</b>								
Prevention of venous thromboembolism								
<b>The Treatment criteria is:</b>								
Patient must be undergoing total hip replacement,								
<b>AND the Clinical criteria is:</b>								

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	Patient must require up to 10 days supply to complete a course of treatment.							
	<b>Note</b>							
	No increase in the maximum quantity or number of units may be authorised.							
	<b>Note</b>							
	No increase in the maximum number of repeats may be authorised.							
	<b>Note</b>							
	<b>Shared Care Model:</b>							
	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.							
5500L NP	apixaban 2.5 mg tablet, 20	1	..	..	39.66	36.90	Eliquis	BQ
	<b>APIXABAN</b>							
	<b>Authority required (STREAMLINED)</b>							
	<b>4382</b>							
	Prevention of venous thromboembolism							
	<b>The Treatment criteria is:</b>							
	Patient must be undergoing total knee replacement,							
	<b>AND the Clinical criteria is:</b>							
	Patient must require up to 15 days of therapy.							
	<b>Authority required (STREAMLINED)</b>							
	<b>4409</b>							
	Prevention of venous thromboembolism							
	<b>The Treatment criteria is:</b>							
	Patient must be undergoing total hip replacement,							
	<b>AND the Clinical criteria is:</b>							
	Patient must require up to 15 days supply to complete a course of treatment.							
	<b>Note</b>							
	No increase in the maximum quantity or number of units may be authorised.							
	<b>Note</b>							
	No increase in the maximum number of repeats may be authorised.							
	<b>Note</b>							
	<b>Shared Care Model:</b>							
	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.							
5054B NP	apixaban 2.5 mg tablet, 30	1	..	..	54.21	36.90	Eliquis	BQ
	<b>APIXABAN</b>							
	<b>Authority required (STREAMLINED)</b>							
	<b>4402</b>							
	Prevention of venous thromboembolism							
	<b>The Treatment criteria is:</b>							
	Patient must be undergoing total hip replacement,							
	<b>AND the Clinical criteria is:</b>							
	Patient must require up to 30 days supply to complete a course of treatment.							
	<b>Note</b>							
	No increase in the maximum quantity or number of units may be authorised.							
	<b>Note</b>							
	No increase in the maximum number of repeats may be authorised.							
	<b>Note</b>							
	<b>Shared Care Model:</b>							
	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.							
5061J NP	apixaban 2.5 mg tablet, 60	1	..	..	101.41	36.90	Eliquis	BQ
	<b>BENZTROPINE</b>							

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
10013B NP	benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials	1	..	..	287.52	36.90	Benztropine Omega	FK
10027R DP	benztropine mesylate 2 mg/2 mL injection, 10 x 2 mL vials	1	..	..	287.52	36.90	Benztropine Omega	FK

### BUDESONIDE + EFORMOTEROL

#### Restricted benefit

Asthma

#### The Clinical criteria is:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids; 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,

#### AND the Population criteria is:

Patient must be aged 12 years or over.

8796Y NP	budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 120 actuations	1	5	..	54.68	36.90	Symbicort Turbuhaler 100/6	AP
8625Y NP	budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: powder for, 120 actuations	1	5	..	58.98	36.90	Symbicort Turbuhaler 200/6	AP

### BUDESONIDE + EFORMOTEROL

#### Restricted benefit

Asthma

#### The Clinical criteria is:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids,

#### AND the Population criteria is:

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.

#### Restricted benefit

Chronic obstructive pulmonary disease (COPD)

#### The Clinical criteria is:

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

#### AND the Clinical criteria is:

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

#### Note

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

10018G NP	budesonide 200 microgram/actuation + eformoterol fumarate dihydrate 6 microgram/actuation inhalation: pressurised, 120 actuations	2	5	..	*90.75	36.90	Symbicort Rapihaler 200/6	AP
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### BUDESONIDE + EFORMOTEROL

#### Restricted benefit

Asthma

#### The Clinical criteria is:

Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids,

#### AND the Population criteria is:

Patient must be aged 12 years or over.

#### Note

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.								
<b>Restricted benefit</b>								
Chronic obstructive pulmonary disease (COPD)								
<b>The Clinical criteria is:</b>								
Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy,								
<b>AND the Clinical criteria is:</b>								
Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy,								
<b>AND the Clinical criteria is:</b>								
The treatment must be for symptomatic treatment.								
<b>Note</b>								
Budesonide with eformoterol fumarate dihydrate is not indicated for the initiation of bronchodilator therapy in COPD.								
8750M NP	budesonide 400 microgram/actuation + eformoterol fumarate dihydrate 12 microgram/actuation inhalation: powder for, 120 actuations	1	5	..	90.76	36.90	Symbicort Turbuhaler 400/12	AP
<b>BUDESONIDE + EFORMOTEROL</b>								
<b>Restricted benefit</b>								
Asthma								
<b>The Clinical criteria is:</b>								
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,								
<b>AND the Population criteria is:</b>								
Patient must be aged 12 years or over.								
10024N NP	budesonide 50 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations	2	5	..	*54.67	36.90	Symbicort Rapihaler 50/3	AP
10015D NP	budesonide 100 microgram/actuation + eformoterol fumarate dihydrate 3 microgram/actuation inhalation: pressurised, 120 actuations	2	5	..	*58.97	36.90	Symbicort Rapihaler 100/3	AP
<b>CANDESARTAN + HYDROCHLOROTHIAZIDE</b>								
<b>Restricted benefit</b>								
Hypertension								
<b>The Clinical criteria is:</b>								
The treatment must not be for the initiation of anti-hypertensive therapy,								
<b>AND the Clinical criteria is:</b>								
The condition must be inadequately controlled with an angiotensin II antagonist; OR								
The condition must be inadequately controlled with a thiazide diuretic.								
8504N NP	candesartan cilexetil 16 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	27.39	28.52	<sup>a</sup> Adesan HCT 16/12.5	AF
							<sup>a</sup> APO-Candesartan HCTZ 16/12.5	TX
							<sup>a</sup> Atacand Plus 16/12.5	AP
							<sup>a</sup> Candesartan/HCT Sandoz	SZ
							<sup>a</sup> Candesartan Combi Aspen 16/12.5	QA
							<sup>a</sup> Candesartan HCT GH 16/12.5	GQ
							<sup>a</sup> Candesartan HCTZ-GA 16/12.5	GN
							<sup>a</sup> Candesartan HCTZ RBX 16/12.5	RA

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
							Pharmacor Candesartan HCT 16/12.5	CR
9314F NP	candesartan cilexetil 32 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	31.33	32.46	APO-Candesartan HCTZ 32/12.5	TX
							Atacand Plus 32/12.5	AP
							Candesartan/HCT Sandoz	SZ
							Candesartan Combi Aspen 32/12.5	QA
							Candesartan HCT GH 32/12.5	GQ
							Candesartan HCTZ-GA 32/12.5	GN
							Candesartan HCTZ RBX 32/12.5	RA
							Pharmacor Candesartan HCT 32/12.5	CR
9315G NP	candesartan cilexetil 32 mg + hydrochlorothiazide 25 mg tablet, 30	1	5	..	33.21	34.34	APO-Candesartan HCTZ 32/25	TX
							Atacand Plus 32/25	AP
							Candesartan/HCT Sandoz	SZ
							Candesartan Combi Aspen 32/25	QA
							Candesartan HCT GH 32/25	GQ
							Candesartan HCTZ-GA 32/25	GN
							Candesartan HCTZ RBX 32/25	RA
							Pharmacor Candesartan HCT 32/25	CR
	<b>CYCLOPHOSPHAMIDE</b>							
10026Q	cyclophosphamide 50 mg tablet, 50	1	2	..	83.51	36.90	Endoxan	BX
	<b>DABIGATRAN</b>							
	<b><u>Authority required (STREAMLINED)</u></b>							
	<b>4402</b>							
	Prevention of venous thromboembolism							
	<b>The Treatment criteria is:</b>							
	Patient must be undergoing total hip replacement,							
	<b>AND the Clinical criteria is:</b>							
	Patient must require up to 30 days supply to complete a course of treatment.							
	<b><u>Note</u></b>							
	No increase in the maximum quantity or number of units may be authorised.							
	<b><u>Note</u></b>							
	No increase in the maximum number of repeats may be authorised.							
	<b><u>Note</u></b>							
	<b>Shared Care Model:</b>							
	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.							
9321N NP	dabigatran etexilate 110 mg capsule, 60	1	..	..	96.12	36.90	Pradaxa	BY
9320M NP	dabigatran etexilate 75 mg capsule, 60	1	..	..	120.88	36.90	Pradaxa	BY
	<b>DABIGATRAN</b>							
	<b><u>Authority required (STREAMLINED)</u></b>							
	<b>4369</b>							
	Prevention of venous thromboembolism							
	<b>The Treatment criteria is:</b>							
	Patient must be undergoing total hip replacement,							

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<b>AND the Clinical criteria is:</b>								
Patient must require up to 20 days supply to complete a course of treatment.								
<b>Note</b>								
No increase in the maximum quantity or number of units may be authorised.								
<b>Note</b>								
No increase in the maximum number of repeats may be authorised.								
<b>Note</b>								
<b>Shared Care Model:</b>								
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.								
9319L NP	dabigatran etexilate 110 mg capsule, 10	2	1	..	*37.81	36.90	Pradaxa	BY
9318K NP	dabigatran etexilate 75 mg capsule, 10	2	1	..	*45.75	36.90	Pradaxa	BY

### DABIGATRAN

#### **Authority required (STREAMLINED)**

**4381**

Prevention of venous thromboembolism

#### **The Treatment criteria is:**

Patient must be undergoing total knee replacement,

#### **AND the Clinical criteria is:**

Patient must require up to 10 days of therapy.

#### **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**

#### **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.

9323Q NP	dabigatran etexilate 110 mg capsule, 10	2	..	..	*37.81	36.90	Pradaxa	BY
9322P NP	dabigatran etexilate 75 mg capsule, 10	2	..	..	*45.75	36.90	Pradaxa	BY

### DIMETHYL FUMARATE

#### **Authority required**

Multiple sclerosis

Treatment Phase: Initial treatment

#### **The Clinical criteria is:**

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

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

#### **AND the Clinical criteria is:**

The treatment must be as monotherapy,

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

Patient must be ambulatory (without assistance or support).

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

#### **Note**

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

#### **Note**

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

## GENERAL PHARMACEUTICAL BENEFITS

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

Special Pricing Arrangements apply.

2896K	dimethyl fumarate 120 mg capsule, 14	1	..	..	491.18	36.90	Tecfidera	BD
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**DIMETHYL FUMARATE****Authority required**

Multiple sclerosis

Treatment Phase: Continuing treatment

**The Clinical criteria is:**

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

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

**AND the Clinical criteria is:**

The treatment must be as monotherapy,

**AND the Clinical criteria is:**

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

Patient must have been receiving treatment with this drug prior to 1 December 2013,

**AND the Clinical criteria is:**

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

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

**Note**

Special Pricing Arrangements apply.

2943X	dimethyl fumarate 120 mg capsule, 14	1	..	..	491.18	36.90	Tecfidera	BD
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**DIMETHYL FUMARATE****Authority required**

Multiple sclerosis

Treatment Phase: Continuing treatment

**The Clinical criteria is:**

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

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

**AND the Clinical criteria is:**

The treatment must be as monotherapy,

**AND the Clinical criteria is:**

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

Patient must have been receiving treatment with this drug prior to 1 December 2013,

**AND the Clinical criteria is:**

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

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

**Note**

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.

2966D	dimethyl fumarate 240 mg capsule, 56	1	5	..	1879.87	36.90	Tecfidera	BD
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**ENALAPRIL + HYDROCHLOROTHIAZIDE****Restricted benefit**

Hypertension

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<b>The Clinical criteria is:</b>								
The treatment must not be for the initiation of anti-hypertensive therapy,								
<b>AND the Clinical criteria is:</b>								
The condition must be inadequately controlled with an ACE inhibitor; OR								
The condition must be inadequately controlled with a thiazide diuretic.								
<b>Caution</b>								
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.								
8477E NP	enalapril maleate 20 mg + hydrochlorothiazide 6 mg tablet, 30	1	5	..	27.81	28.94	<sup>a</sup> Enalapril/HCT Sandoz  <sup>a</sup> Renitec Plus 20/6	SZ  MK

### EPROSARTAN + HYDROCHLOROTHIAZIDE

#### Restricted benefit

Hypertension

#### **The Clinical criteria is:**

The treatment must not be for the initiation of anti-hypertensive therapy,

#### **AND the Clinical criteria is:**

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

8624X NP	eprosartan 600 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	26.51	27.64	Teveten Plus 600/12.5	AB
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### ERLOTINIB

#### Authority required

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

Treatment Phase: Initial treatment

#### **The Clinical criteria is:**

The treatment must be as monotherapy,

#### **AND the Clinical criteria is:**

The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC,

#### **AND the Clinical criteria is:**

Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR

Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal,

#### **AND the Clinical criteria is:**

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

#### **AND the Population criteria is:**

Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

#### Authority required

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

Treatment Phase: Continuing treatment

#### **The Clinical criteria is:**

The treatment must be as monotherapy,

#### **AND the Clinical criteria is:**

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

#### **AND the Clinical criteria is:**

Patient must not have progressive disease,

#### **AND the Population criteria is:**

Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.

#### Note

Special Pricing Arrangements apply.

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
10022L	erlotinib 25 mg tablet, 30	1	3	..	794.40	36.90	Tarceva	RO
10020J	erlotinib 100 mg tablet, 30	1	3	..	2703.55	36.90	Tarceva	RO
10014C	erlotinib 150 mg tablet, 30	1	3	..	3309.87	36.90	Tarceva	RO

### ERLOTINIB

#### **Authority required**

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

Treatment Phase: Continuing treatment

#### **The Clinical criteria is:**

The treatment must be as monotherapy,

#### **AND the Clinical criteria is:**

Patient must have previously been issued with an authority prescription for this drug prior to 1 January 2014,

#### **AND the Clinical criteria is:**

Patient must not have progressive disease,

#### **AND the Population criteria is:**

Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR

Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

#### **Note**

Special Pricing Arrangements apply.

10028T	erlotinib 25 mg tablet, 30	1	3	..	794.40	36.90	Tarceva	RO
10019H	erlotinib 100 mg tablet, 30	1	3	..	2703.55	36.90	Tarceva	RO
10025P	erlotinib 150 mg tablet, 30	1	3	..	3309.87	36.90	Tarceva	RO

### ERLOTINIB

#### **Authority required**

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

Treatment Phase: Initial treatment

#### **The Clinical criteria is:**

The treatment must be as monotherapy,

#### **AND the Clinical criteria is:**

Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR

Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal,

#### **AND the Clinical criteria is:**

Patient must have failed prior therapy which included a platinum compound,

#### **AND the Clinical criteria is:**

Patient must have a WHO performance status of 3 or less,

#### **AND the Clinical criteria is:**

The condition must have progressed following treatment with docetaxel or pemetrexed; OR

Patient must have a contraindication or intolerance to treatment with docetaxel and pemetrexed,

#### **AND the Clinical criteria is:**

Patient must not be able to receive further chemotherapy subsidised by the PBS or from other sources following treatment with erlotinib,

#### **AND the Population criteria is:**

Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR

Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.

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

(1) a completed authority prescription form; and

(2) a completed Non-Small Cell Lung Cancer Erlotinib Authority Application - Supporting Information Form, which includes:

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	<p>(i) evidence that the patient has been treated with platinum-based chemotherapy; AND</p> <p>(ii) evidence that disease progression has occurred following treatment with docetaxel or pemetrexed. In patients in whom docetaxel or pemetrexed is contraindicated or cannot be tolerated the prescriber must state the reasons for intolerance or the contraindication; AND</p> <p>(iii) a declaration from the prescriber that the patient has exhausted all opportunities for treatment with chemotherapy either on the PBS, through special access schemes or in a clinical trial; and</p> <p>(3) a signed patient acknowledgement.</p> <p><b>Authority required</b>            Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)            Treatment Phase: Continuing treatment</p> <p><b>The Clinical criteria is:</b>            The treatment must be as monotherapy,</p> <p><b>AND the Clinical criteria is:</b>            Patient must have previously been issued with an authority prescription for this drug,</p> <p><b>AND the Clinical criteria is:</b>            Patient must not have progressive disease,</p> <p><b>AND the Population criteria is:</b>            Patient must have a wild type epidermal growth factor receptor (EGFR) gene; OR            Patient must have an epidermal growth factor receptor (EGFR) gene of unknown type.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Non-Small Cell Lung Cancer Erlotinib Authority Application - Supporting Information Form, which includes:</p> <p>(i) evidence that the patient has been treated with platinum-based chemotherapy; AND</p> <p>(ii) evidence that disease progression has occurred following treatment with docetaxel or pemetrexed. In patients in whom docetaxel or pemetrexed is contraindicated or cannot be tolerated the prescriber must state the reasons for intolerance or the contraindication; AND</p> <p>(iii) a declaration from the prescriber that the patient has exhausted all opportunities for treatment with chemotherapy either on the PBS, through special access schemes or in a clinical trial; and</p> <p>(3) a signed patient acknowledgement.</p> <p><b>Note</b>            Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:            Department of Human Services            Prior Written Approval of Complex Drugs            Reply Paid 9826            GPO Box 9826            HOBART TAS 7001</p> <p><b>Note</b>            Special Pricing Arrangements apply.</p>						
9166K	erlotinib 25 mg tablet, 30	1	3	..	794.40	36.90	Tarceva RO
9167L	erlotinib 100 mg tablet, 30	1	3	..	2703.55	36.90	Tarceva RO
9168M	erlotinib 150 mg tablet, 30	1	3	..	3309.87	36.90	Tarceva RO

### EXENATIDE

#### **Authority required (STREAMLINED)**

**4392**

Diabetes mellitus type 2

#### **The Clinical criteria is:**

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

## GENERAL PHARMACEUTICAL BENEFITS

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

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

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

**AND the Clinical criteria is:**

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

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

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

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

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

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

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

**Authority required (STREAMLINED)**

**4405**

Diabetes mellitus type 2

**The Clinical criteria is:**

The treatment must be in combination with metformin,

**AND the Clinical criteria is:**

The treatment must be in combination with a sulfonylurea,

**AND the Clinical criteria is:**

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

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

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

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

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

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

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

**Note**

This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), an insulin or an SGLT2 inhibitor.

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<b>Note</b>								
Special Pricing Arrangements apply.								
3423E NP	exenatide 5 microgram/20 microlitre injection, 60 unit doses	1	5	..	122.66	36.90	Byetta 5 microgram	BQ
3424F NP	exenatide 10 microgram/40 microlitre injection, 60 unit doses	1	5	..	131.52	36.90	Byetta 10 microgram	BQ
<b>FLUTICASONE + EFORMOTEROL</b>								
<b>Restricted benefit</b>								
Asthma								
<b>The Clinical criteria is:</b>								
Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids,								
<b>AND the Population criteria is:</b>								
Patient must be aged 12 years or over.								
<b>Note</b>								
Flutiform is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.								
<b>Note</b>								
Flutiform is not indicated or PBS-subsidised for bronchodilator therapy in COPD.								
2827T NP	fluticasone propionate 50 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations	1	5	..	45.83	36.90	flutiform 50/5	MF
10007Q NP	fluticasone propionate 125 microgram/actuation + eformoterol fumarate dihydrate 5 microgram/actuation inhalation: pressurised, 120 actuations	1	5	..	56.58	36.90	flutiform 125/5	MF
10008R NP	fluticasone propionate 250 microgram/actuation + eformoterol fumarate dihydrate 10 microgram/actuation inhalation: pressurised, 120 actuations	1	5	..	78.65	36.90	flutiform 250/10	MF
<b>FLUTICASONE + SALMETEROL</b>								
<b>Restricted benefit</b>								
Asthma								
<b>The Clinical criteria is:</b>								
Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids,								
<b>AND the Clinical criteria is:</b>								
Patient must have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate if aged less than 12 years.								
<b>Restricted benefit</b>								
Chronic obstructive pulmonary disease (COPD)								
<b>The Clinical criteria is:</b>								
Patient must have a forced expiratory volume in 1 second (FEV1) less than 50% of predicted normal prior to therapy,								
<b>AND the Clinical criteria is:</b>								
Patient must have a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy,								
<b>AND the Clinical criteria is:</b>								
The treatment must be for symptomatic treatment.								
<b>Note</b>								
Seretide is not indicated for the initiation of bronchodilator therapy in COPD.								
8519J NP	fluticasone propionate 250 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations	1	5	..	78.65	36.90	Seretide MDI 250/25	GK
8432T NP	fluticasone propionate 500 microgram/actuation + salmeterol 50	1	5	..	78.65	36.90	Seretide Accuhaler 500/50	GK

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	microgram/actuation inhalation: powder for, 60 actuations							
<b>FLUTICASONE + SALMETEROL</b>								
<b><u>Restricted benefit</u></b>								
Asthma								
<b>The Clinical criteria is:</b>								
Patient must have previously had frequent episodes of asthma while receiving treatment with oral corticosteroids or optimal doses of inhaled corticosteroids,								
<b>AND the Clinical criteria is:</b>								
Patient must have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate if aged less than 12 years.								
8517G NP	fluticasone propionate 50 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations	1	5	..	47.41	36.90	Seretide MDI 50/25	GK
8518H NP	fluticasone propionate 125 microgram/actuation + salmeterol 25 microgram/actuation inhalation: pressurised, 120 actuations	1	5	..	59.52	36.90	Seretide MDI 125/25	GK
8430Q NP	fluticasone propionate 100 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations	1	5	..	47.41	36.90	Seretide Accuhaler 100/50	GK
8431R NP	fluticasone propionate 250 microgram/actuation + salmeterol 50 microgram/actuation inhalation: powder for, 60 actuations	1	5	..	59.52	36.90	Seretide Accuhaler 250/50	GK
<b>FOSINOPRIL + HYDROCHLOROTHIAZIDE</b>								
<b><u>Restricted benefit</u></b>								
Hypertension								
<b>The Clinical criteria is:</b>								
The treatment must not be for the initiation of anti-hypertensive therapy,								
<b>AND the Clinical criteria is:</b>								
The condition must be inadequately controlled with an ACE inhibitor; OR								
The condition must be inadequately controlled with a thiazide diuretic.								
<b><u>Caution</u></b>								
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.								
8400D NP	fosinopril sodium 10 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	21.53	22.66	<sup>a</sup> APO-Fosinopril HCTZ 10/12.5	TX
							<sup>a</sup> Fosinopril/HCTZ-GA 10/12.5	GN
							<sup>a</sup> Hyforil	RA
							<sup>a</sup> Monoplus 10/12.5	BQ
8401E NP	fosinopril sodium 20 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	28.51	29.64	<sup>a</sup> APO-Fosinopril HCTZ 20/12.5	TX
							<sup>a</sup> Fosetic 20/12.5	ZP
							<sup>a</sup> Fosinopril/HCT Actavis 20/12.5	UA
							<sup>a</sup> Fosinopril/HCTZ-GA 20/12.5	GN
							<sup>a</sup> Hyforil	RA
							<sup>a</sup> Monoplus 20/12.5	BQ

### GEFITINIB

#### **Authority required**

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

Treatment Phase: Initial treatment

#### **The Clinical criteria is:**

The treatment must be as monotherapy,

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<b>AND the Clinical criteria is:</b>							
The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC,							
<b>AND the Clinical criteria is:</b>							
Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR							
Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal,							
<b>AND the Clinical criteria is:</b>							
Patient must have a WHO performance status of 2 or less,							
<b>AND the Population criteria is:</b>							
Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material.							
<b>Authority required</b>							
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)							
Treatment Phase: Continuing treatment							
<b>The Clinical criteria is:</b>							
The treatment must be as monotherapy,							
<b>AND the Clinical criteria is:</b>							
Patient must have previously been issued with an authority prescription for this drug,							
<b>AND the Clinical criteria is:</b>							
Patient must not have progressive disease.							
<b>Note</b>							
Special Pricing Arrangements apply.							
8769M	gefitinib 250 mg tablet, 30	1	3	..	3851.57	36.90	Iressa AP
<b>IRBESARTAN + HYDROCHLOROTHIAZIDE</b>							
<b>Restricted benefit</b>							
Hypertension							
<b>The Clinical criteria is:</b>							
The treatment must not be for the initiation of anti-hypertensive therapy,							
<b>AND the Clinical criteria is:</b>							
The condition must be inadequately controlled with an angiotensin II antagonist; OR							
The condition must be inadequately controlled with a thiazide diuretic.							
8404H NP	irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	18.14	19.27	<sup>a</sup> Abisart HCT 150/12.5 AF
							<sup>a</sup> APO-Irbesartan HCTZ TX
							<sup>a</sup> Avapro HCT 150/12.5 AV
							<sup>a</sup> Chem mart Irbesartan HCTZ CH
							<sup>a</sup> Irbesartan/HCT Sandoz SZ
							<sup>a</sup> Irbesartan/HCTZ RBX 150/12.5 RA
							<sup>a</sup> Irbesartan HCT Winthrop 150/12.5 WA
							<sup>a</sup> Irbesartan HCTZ-GA 150/12.5 GN
							<sup>a</sup> Irbesartide GH 150/12.5 GQ
							<sup>a</sup> Karvezide 150/12.5 SW
							<sup>a</sup> KSART HCT 150/12.5 QA
							<sup>a</sup> Terry White Chemists Irbesartan HCTZ TW
8405J NP	irbesartan 300 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	27.77	28.90	<sup>a</sup> Abisart HCT 300/12.5 AF
							<sup>a</sup> APO-Irbesartan HCTZ TX
							<sup>a</sup> Avapro HCT 300/12.5 AV

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							Chem mart Irbesartan HCTZ	CH
							Irbesartan/HCT Sandoz	SZ
							Irbesartan/HCTZ RBX 300/12.5	RA
							Irbesartan HCT Winthrop 300/12.5	WA
							Irbesartan HCTZ-GA 300/12.5	GN
							Irbesatzide GH 300/12.5	GQ
							Karvezide 300/12.5	SW
							KSART HCT 300/12.5	QA
							Terry White Chemists Irbesartan HCTZ	TW
2136K NP	irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30	1	5	..	29.64	30.77	Abisart HCT 300/25	AF
							APO-Irbesartan HCTZ	TX
							Avapro HCT 300/25	AV
							Chem mart Irbesartan HCTZ	CH
							Irbesartan/HCT Sandoz	SZ
							Irbesartan/HCTZ RBX 300/25	RA
							Irbesartan HCT Winthrop 300/25	WA
							Irbesartan HCTZ-GA 300/25	GN
							Irbesatzide GH 300/25	GQ
							Karvezide 300/25	SW
							KSART HCT 300/25	QA
							Terry White Chemists Irbesartan HCTZ	TW

### LERCANIDIPINE + ENALAPRIL

#### Restricted benefit

Hypertension

#### The Clinical criteria is:

The treatment must not be for the initiation of anti-hypertensive therapy,

#### AND the Clinical criteria is:

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

#### Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

9144G NP	lercanidipine hydrochloride 10 mg + enalapril maleate 10 mg tablet, 28	1	5	..	16.55	17.68	Zan-Extra 10/10	AB
9145H NP	lercanidipine hydrochloride 10 mg + enalapril maleate 20 mg tablet, 28	1	5	..	18.08	19.21	Zan-Extra 10/20	AB

### OLMESARTAN MEDOXOMIL + AMLODIPINE

#### Restricted benefit

Hypertension

#### The Clinical criteria is:

The treatment must not be for the initiation of anti-hypertensive therapy,

#### AND the Clinical criteria is:

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

5292M NP	olmesartan medoxomil 20 mg + amlodipine 5 mg tablet, 30	1	5	..	18.83	19.96	Sevikar 20/5	MK
5294P NP	olmesartan medoxomil 40 mg + amlodipine 10 mg tablet, 30	1	5	..	31.41	32.54	Sevikar 40/10	MK
5293N NP	olmesartan medoxomil 40 mg + amlodipine 5 mg tablet, 30	1	5	..	29.14	30.27	Sevikar 40/5	MK

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### OLMESARTAN MEDOXOMIL + HYDROCHLOROTHIAZIDE

#### Restricted benefit

Hypertension

#### The Clinical criteria is:

The treatment must not be for the initiation of anti-hypertensive therapy,

#### AND the Clinical criteria is:

The condition must be inadequately controlled with an angiotensin II antagonist; OR

The condition must be inadequately controlled with a thiazide diuretic.

2161R NP	olmesartan medoxomil 20 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	18.03	19.16	Olmetec Plus	MK
2166B NP	olmesartan medoxomil 40 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	28.33	29.46	Olmetec Plus	MK
2170F NP	olmesartan medoxomil 40 mg + hydrochlorothiazide 25 mg tablet, 30	1	5	..	30.57	31.70	Olmetec Plus	MK

### PERINDOPRIL + AMLODIPINE

#### Restricted benefit

Hypertension

#### The Clinical criteria is:

The treatment must not be for the initiation of anti-hypertensive therapy,

#### AND the Clinical criteria is:

The condition must be inadequately controlled with an ACE inhibitor; OR

The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.

#### Restricted benefit

Stable coronary heart disease

#### The Clinical criteria is:

The treatment must not be for the initiation of therapy for coronary heart disease,

#### AND the Clinical criteria is:

The condition must be stabilised by treatment with perindopril and amlodipine at the same doses.

#### Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

9346X NP	perindopril arginine 5 mg + amlodipine 5 mg tablet, 30	1	5	..	27.32	28.45	<sup>a</sup> Coveram 5/5	SE
							<sup>a</sup> Reaptan 5/5	RX
9347Y NP	perindopril arginine 5 mg + amlodipine 10 mg tablet, 30	1	5	..	34.66	35.79	<sup>a</sup> Coveram 5/10	SE
							<sup>a</sup> Reaptan 5/10	RX
9348B NP	perindopril arginine 10 mg + amlodipine 5 mg tablet, 30	1	5	..	33.15	34.28	<sup>a</sup> Coveram 10/5	SE
							<sup>a</sup> Reaptan 10/5	RX
9349C NP	perindopril arginine 10 mg + amlodipine 10 mg tablet, 30	1	5	..	40.47	36.90	<sup>a</sup> Coveram 10/10	SE
							<sup>a</sup> Reaptan 10/10	RX

### PERINDOPRIL + INDAPAMIDE

#### Restricted benefit

Hypertension

#### The Clinical criteria is:

The treatment must not be for the initiation of anti-hypertensive therapy,

#### AND the Clinical criteria is:

The condition must be inadequately controlled with a thiazide-like diuretic; OR

The condition must be inadequately controlled with an ACE inhibitor.

#### Caution

Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.

#### Note

Pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 4 mg perindopril erbumine-1.25 mg

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indapamide hemihydrate) and pharmaceutical benefits that have the form perindopril with indapamide hemihydrate tablet (containing 5 mg perindopril arginine-1.25 mg indapamide hemihydrate) are equivalent for the purposes of substitution.								
2845R NP	perindopril arginine 5 mg + indapamide hemihydrate 1.25 mg tablet, 30	1	5	..	25.90	27.03	<sup>a</sup> Coversyl Plus 5mg/1.25mg <sup>a</sup> Prexum Combi 5/1.25	SE RX
8449Q NP	perindopril erbumine 4 mg + indapamide hemihydrate 1.25 mg tablet, 30	1	5	..	25.90	27.03	<sup>a</sup> Chem mart Perindopril/ Indapamide 4/1.25 <sup>a</sup> GenRx Perindopril/ Indapamide 4/1.25 <sup>a</sup> Idaprex Combi 4/1.25 <sup>a</sup> Indosyl Combi 4/1.25 <sup>a</sup> Perindo Combi 4/1.25 <sup>a</sup> Perindopril/ Indapamide GH 4/1.25 <sup>a</sup> Terry White Chemists Perindopril/ Indapamide 4/1.25	CH GX SZ QA AF GQ TW

### PIOGLITAZONE

#### **Authority required (STREAMLINED)**

**4363**

Diabetes mellitus type 2

#### **The Clinical criteria is:**

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

#### **AND the Clinical criteria is:**

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

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

#### **AND the Clinical criteria is:**

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

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

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

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

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

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

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

#### **Authority required (STREAMLINED)**

**4388**

Diabetes mellitus type 2

#### **The Clinical criteria is:**

The treatment must be in combination with insulin,

#### **AND the Clinical criteria is:**

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

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oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR

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

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

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

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

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

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

### **Authority required (STREAMLINED)**

**4364**

Diabetes mellitus type 2

#### **The Clinical criteria is:**

The treatment must be in combination with metformin,

#### **AND the Clinical criteria is:**

The treatment must be in combination with a sulfonylurea,

#### **AND the Clinical criteria is:**

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

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

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

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

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

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

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

### **Note**

This drug is not PBS-subsidised for use as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1 or an SGLT2 inhibitor.

8694N NP	pioglitazone 15 mg tablet, 28	1	5	..	40.93	36.90	<sup>a</sup>	Acpio 15	QA
							<sup>a</sup>	Actos	LY
							<sup>a</sup>	APOTEX-Pioglitazone	TX
							<sup>a</sup>	Chem mart Pioglitazone	CH
							<sup>a</sup>	Pharmacor Pioglitazone 15	CR
							<sup>a</sup>	Pioglitazone-GA	GN

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							<sup>a</sup> Pioglitazone generichealth 15 GQ
							<sup>a</sup> Pioglitazone Sandoz SZ
							<sup>a</sup> Pizaccord RA
							<sup>a</sup> Prioten 15 DO
							<sup>a</sup> Terry White Chemists Pioglitazone TW
							<sup>a</sup> Vexazone AF
8695P NP	pioglitazone 30 mg tablet, 28	1	5	..	57.10	36.90	<sup>a</sup> Acpio 30 QA
							<sup>a</sup> Actos LY
							<sup>a</sup> APOTEX-Pioglitazone TX
							<sup>a</sup> Chem mart Pioglitazone CH
							<sup>a</sup> Pharmacor Pioglitazone 30 CR
							<sup>a</sup> Pioglitazone-GA GN
							<sup>a</sup> Pioglitazone generichealth 30 GQ
							<sup>a</sup> Pioglitazone Sandoz SZ
							<sup>a</sup> Pizaccord RA
							<sup>a</sup> Prioten 30 DO
							<sup>a</sup> Terry White Chemists Pioglitazone TW
							<sup>a</sup> Vexazone AF
8696Q NP	pioglitazone 45 mg tablet, 28	1	5	..	72.25	36.90	<sup>a</sup> Acpio 45 QA
							<sup>a</sup> Actos LY
							<sup>a</sup> APOTEX-Pioglitazone TX
							<sup>a</sup> Chem mart Pioglitazone CH
							<sup>a</sup> Pharmacor Pioglitazone 45 CR
							<sup>a</sup> Pioglitazone-GA GN
							<sup>a</sup> Pioglitazone generichealth 45 GQ
							<sup>a</sup> Pioglitazone Sandoz SZ
							<sup>a</sup> Pizaccord RA
							<sup>a</sup> Prioten 45 DO
							<sup>a</sup> Terry White Chemists Pioglitazone TW
							<sup>a</sup> Vexazone AF

### PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES

#### Authority required

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

#### The Treatment criteria is:

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

#### AND the Clinical criteria is:

The condition must not be isolated infant colic or reflux,

#### AND the Clinical criteria is:

Patient must have failed to respond to a strict soy-based cows' milk protein free diet,

#### AND the Population criteria is:

Patient must be up to the age of 24 months.

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

#### Authority required

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

#### The Treatment criteria is:

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

## GENERAL PHARMACEUTICAL BENEFITS

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in consultation with a specialist allergist, clinical immunologist, specialist paediatrician or specialist paediatric gastroenterologist and hepatologist,

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Clinical criteria is:**

Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides,

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

Cows' milk protein enteropathy and intolerance to soy protein

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Clinical criteria is:**

Patient must have failed to respond to a strict soy-based cows' milk protein free diet,

**AND the Population criteria is:**

Patient must be older than 24 months of age.

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

**Authority required**

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

Treatment Phase: Initial treatment for up to 6 months

**The Treatment criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

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

Treatment Phase: Continuing treatment

**The Treatment criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

Biliary atresia

**Authority required**

Chronic liver failure with fat malabsorption

**Authority required**

Chylous ascites

**Authority required**

Cystic fibrosis

**Authority required**

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Enterokinase deficiency

**Authority required**

Proven fat malabsorption

**Authority required**

Severe diarrhoea of greater than 2 weeks duration

**The Population criteria is:**

Patient must be aged less than 4 months.

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

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Authority required**

Chylothorax

**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.

2676W NP	protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 400 g	8	5	..	*172.15	36.90	Alfaré	NT
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**PROTEIN HYDROLYSATE FORMULA WITH MEDIUM CHAIN TRIGLYCERIDES**

**Authority required**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Initial treatment

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Clinical criteria is:**

Patient must have failed to respond to a strict soy-based cows' milk protein free diet,

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

Cows' milk protein enteropathy and intolerance to soy protein

Treatment Phase: Continuing treatment

**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Clinical criteria is:**

Patient must have demonstrated a clinical improvement with the protein hydrolysate formula with medium chain triglycerides,

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

Cows' milk protein enteropathy and intolerance to soy protein

## GENERAL PHARMACEUTICAL BENEFITS

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**The Treatment criteria is:**

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

**AND the Clinical criteria is:**

The condition must not be isolated infant colic or reflux,

**AND the Clinical criteria is:**

Patient must have failed to respond to a strict soy-based cows' milk protein free diet,

**AND the Population criteria is:**

Patient must be older than 24 months of age.

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

**Authority required**

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

Treatment Phase: Initial treatment for up to 6 months

**The Treatment criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

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

Treatment Phase: Continuing treatment

**The Treatment criteria is:**

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

**AND the Population criteria is:**

Patient must be up to the age of 24 months.

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

**Authority required**

Biliary atresia

**Authority required**

Chronic liver failure with fat malabsorption

**Authority required**

Chylous ascites

**Authority required**

Cystic fibrosis

**Authority required**

Enterokinase deficiency

**Authority required**

Proven fat malabsorption

**Authority required**

Severe diarrhoea of greater than 2 weeks duration

**The Population criteria is:**

Patient must be aged less than 4 months.

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

**Authority required**

Severe intestinal malabsorption including short bowel syndrome

**Note**

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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No increase in the maximum quantity or number of units may be authorised.

**Note**

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

8259Q NP	protein hydrolysate formula with medium chain triglycerides oral liquid: powder for, 450 g	8	5	..	*110.07	36.90	Karicare Aptamil Pepti-Junior Gold	NU
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**QUETIAPINE**

**Authority required (STREAMLINED)**

**4391**

Schizophrenia

**The Clinical criteria is:**

The treatment must be for dose titration purposes.

**Authority required (STREAMLINED)**

**4396**

Acute mania

**The Clinical criteria is:**

The condition must be associated with bipolar I disorder,

**AND the Clinical criteria is:**

The treatment must be as monotherapy,

**AND the Clinical criteria is:**

The treatment must be for dose titration purposes.

**Authority required (STREAMLINED)**

**4385**

Bipolar I disorder

**The Clinical criteria is:**

The treatment must be maintenance therapy,

**AND the Clinical criteria is:**

The treatment must be for dose titration purposes.

**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**

**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.

8456C NP	quetiapine 25 mg tablet, 60	1	..	..	36.29	36.90	<sup>a</sup> APO-Quetiapine	TX
							<sup>a</sup> Chem mart Quetiapine	CH
							<sup>a</sup> Delucon 25	DO
							<sup>a</sup> Pharmacy Choice Quetiapine	RI
							<sup>a</sup> Quetiaccord	UA
							<sup>a</sup> Quetiapine Actavis 25	TA
							<sup>a</sup> Quetiapine-DRLA	RZ
							<sup>a</sup> Quetiapine-GA	GN
							<sup>a</sup> Quetiapine GH 25	GQ
							<sup>a</sup> Quetiapine RBX	RA
							<sup>a</sup> Quetiapine Sandoz	SZ
							<sup>a</sup> Quipine	VN
							<sup>a</sup> Sequase	PM
							<sup>a</sup> Seronia 25	QA
							<sup>a</sup> Seroquel	AP
							<sup>a</sup> Syquet	AF
							<sup>a</sup> Terry White Chemists Quetiapine	TW

**QUINAPRIL + HYDROCHLOROTHIAZIDE**

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
	<b><u>Restricted benefit</u></b> Hypertension							
	<b>The Clinical criteria is:</b> The treatment must not be for the initiation of anti-hypertensive therapy,							
	<b>AND the Clinical criteria is:</b> The condition must be inadequately controlled with an ACE inhibitor; OR The condition must be inadequately controlled with a thiazide diuretic.							
	<b><u>Caution</u></b> Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.							
8589C NP	quinapril 10 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	15.32	16.45	Accuretic 10/12.5mg	PF
8590D NP	quinapril 20 mg + hydrochlorothiazide 12.5 mg tablet, 30	1	5	..	16.85	17.98	Accuretic 20/12.5mg	PF
	<b>RAMIPRIL + FELODIPINE</b>							
	<b><u>Restricted benefit</u></b> Hypertension							
	<b>The Clinical criteria is:</b> The treatment must not be for the initiation of anti-hypertensive therapy,							
	<b>AND the Clinical criteria is:</b> The condition must be inadequately controlled with an ACE inhibitor; OR The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.							
	<b><u>Caution</u></b> Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.							
2626F NP	ramipril 2.5 mg + felodipine 2.5 mg tablet: modified release, 30 tablets	1	5	..	15.39	16.52	Triasyn 2.5/2.5	SW
2629J NP	ramipril 5 mg + felodipine 5 mg tablet: modified release, 30 tablets	1	5	..	18.59	19.72	Triasyn 5.0/5.0	SW
	<b>RIVAROXABAN</b>							
	<b><u>Authority required (STREAMLINED)</u></b> <b>4402</b> Prevention of venous thromboembolism							
	<b>The Treatment criteria is:</b> Patient must be undergoing total hip replacement,							
	<b>AND the Clinical criteria is:</b> Patient must require up to 30 days supply to complete a course of treatment.							
	<b><u>Note</u></b> No increase in the maximum quantity or number of units may be authorised.							
	<b><u>Note</u></b> No increase in the maximum number of repeats may be authorised.							
	<b><u>Note</u></b> <b>Shared Care Model:</b> 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.							
9467G NP	RIVAROXABAN Tablet 10 mg, 30	1	..	..	101.01	36.90	Xarelto	BN
9466F NP	rivaroxaban 10 mg tablet, 15	1	1	..	54.03	36.90	Xarelto	BN
	<b>RIVAROXABAN</b>							
	<b><u>Authority required (STREAMLINED)</u></b> <b>4369</b> Prevention of venous thromboembolism							
	<b>The Treatment criteria is:</b> Patient must be undergoing total hip replacement,							
	<b>AND the Clinical criteria is:</b> Patient must require up to 20 days supply to complete a course of treatment.							

## GENERAL PHARMACEUTICAL BENEFITS

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

9465E NP	rivaroxaban 10 mg tablet, 10	1	1	..	39.52	36.90	Xarelto	BN
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**RIVAROXABAN****Authority required (STREAMLINED)****4381**

Prevention of venous thromboembolism

**The Treatment criteria is:**

Patient must be undergoing total knee replacement,

**AND the Clinical criteria is:**

Patient must require up to 10 days of therapy.

**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****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.

9468H NP	rivaroxaban 10 mg tablet, 10	1	..	..	39.52	36.90	Xarelto	BN
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**RIVAROXABAN****Authority required (STREAMLINED)****4382**

Prevention of venous thromboembolism

**The Treatment criteria is:**

Patient must be undergoing total knee replacement,

**AND the Clinical criteria is:**

Patient must require up to 15 days of therapy.

**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****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.

9469J NP	rivaroxaban 10 mg tablet, 15	1	..	..	54.03	36.90	Xarelto	BN
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**ROSIGLITAZONE****Authority required**

Diabetes mellitus type 2

**The Clinical criteria is:**

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

**AND the Clinical criteria is:**

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

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
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Patient must not have tolerated a combination of metformin and a sulfonylurea,

**AND the Clinical criteria is:**

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

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

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

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

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

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

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

**Note**

This drug is not PBS-subsidised for use in combination with metformin and a sulfonylurea (triple oral therapy), as monotherapy or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor.

8689H NP	rosiglitazone 4 mg tablet, 28	1	5	..	61.36	36.90	Avandia	GK
8690J NP	rosiglitazone 8 mg tablet, 28	1	5	..	90.81	36.90	Avandia	GK

**ROSIGLITAZONE + METFORMIN**

**Authority required**

Diabetes mellitus type 2

**The Clinical criteria is:**

Patient must have a contraindication to a sulfonylurea; OR

Patient must not have tolerated a sulfonylurea,

**AND the Clinical criteria is:**

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

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

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

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

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

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

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

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<b>Note</b>								
This fixed dose combination tablet is not PBS-subsidised for use in combination with a sulfonylurea (triple oral therapy), or in combination with a dipeptidyl peptidase 4 inhibitor (gliptin), a glucagon-like peptide-1, an insulin or an SGLT2 inhibitor.								
9060W NP	rosiglitazone 2 mg + metformin hydrochloride 1 g tablet, 56	1	5	..	65.98	36.90	Avandamet	GK
9059T NP	rosiglitazone 2 mg + metformin hydrochloride 500 mg tablet, 56	1	5	..	63.74	36.90	Avandamet	GK
9062Y NP	rosiglitazone 4 mg + metformin hydrochloride 1 g tablet, 56	1	5	..	95.44	36.90	Avandamet	GK
9061X NP	rosiglitazone 4 mg + metformin hydrochloride 500 mg tablet, 56	1	5	..	93.20	36.90	Avandamet	GK
<b>TELMISARTAN + AMLODIPINE</b>								
<b>Restricted benefit</b>								
Hypertension								
<b>The Clinical criteria is:</b>								
The treatment must not be for the initiation of anti-hypertensive therapy,								
<b>AND the Clinical criteria is:</b>								
The condition must be inadequately controlled with an angiotensin II antagonist; OR								
The condition must be inadequately controlled with a dihydropyridine calcium channel blocker.								
8978M NP	telmisartan 40 mg + amlodipine 5 mg tablet, 28	1	5	..	15.97	17.10	Twynsta	BY
8979N NP	telmisartan 40 mg + amlodipine 10 mg tablet, 28	1	5	..	18.08	19.21	Twynsta	BY
8980P NP	telmisartan 80 mg + amlodipine 5 mg tablet, 28	1	5	..	28.34	29.47	Twynsta	BY
8981Q NP	telmisartan 80 mg + amlodipine 10 mg tablet, 28	1	5	..	30.46	31.59	Twynsta	BY
<b>TELMISARTAN + HYDROCHLOROTHIAZIDE</b>								
<b>Restricted benefit</b>								
Hypertension								
<b>The Clinical criteria is:</b>								
The treatment must not be for the initiation of anti-hypertensive therapy,								
<b>AND the Clinical criteria is:</b>								
The condition must be inadequately controlled with an angiotensin II antagonist; OR								
The condition must be inadequately controlled with a thiazide diuretic.								
8622T NP	telmisartan 40 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	14.89	16.02	<sup>a</sup> Pritor Plus 40/12.5 mg	FI
				<sup>b</sup> 2.50	17.39	16.02	<sup>a</sup> Micardis Plus 40/12.5 mg	BY
8623W NP	telmisartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	27.27	28.40	<sup>a</sup> Pritor Plus 80/12.5 mg	FI
				<sup>b</sup> 2.50	29.77	28.40	<sup>a</sup> Micardis Plus 80/12.5 mg	BY
9381R NP	telmisartan 80 mg + hydrochlorothiazide 25 mg tablet, 28	1	5	..	29.01	30.14	<sup>a</sup> Pritor Plus 80/25 mg	FI
				<sup>b</sup> 2.51	31.52	30.14	<sup>a</sup> Micardis Plus 80/25 mg	BY

### TERIPARATIDE

#### Authority required

Severe established osteoporosis

Treatment Phase: Initial treatment

#### The Treatment criteria is:

Must be treated by a specialist; OR

Must be treated by a consultant physician,

#### AND the Clinical criteria is:

Patient must be at very high risk of fracture,

#### AND the Clinical criteria is:

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer
	<p>Patient must have a bone mineral density (BMD) T-score of -3.0 or less,</p> <p><b>AND the Clinical criteria is:</b></p> <p>Patient must have had 2 or more fractures due to minimal trauma,</p> <p><b>AND the Clinical criteria is:</b></p> <p>Patient must have experienced at least 1 symptomatic new fracture after at least 12 months continuous therapy with an anti-resorptive agent at adequate doses,</p> <p><b>AND the Clinical criteria is:</b></p> <p>The treatment must be the sole PBS-subsidised agent,</p> <p><b>AND the Clinical criteria is:</b></p> <p>The treatment must not exceed a lifetime maximum of 18 months therapy.</p> <p>A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.</p> <p>If treatment with anti-resorptive therapy is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be documented in the patient's medical record at the time treatment with teriparatide is initiated.</p> <p>If an intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use of one anti-resorptive agent, alternate anti-resorptive agents must be trialled so that the patient achieves the minimum requirement of 12 months continuous therapy. Details must be documented in the patient's medical record at the time treatment with teriparatide is initiated.</p> <p>Anti-resorptive therapies for osteoporosis and their adequate doses which will be accepted for the purposes of administering this restriction are alendronate sodium 10 mg per day or 70 mg once weekly, risedronate sodium 5 mg per day or 35 mg once weekly or 150 mg once monthly, raloxifene hydrochloride 60 mg per day (women only), denosumab 60 mg once every 6 months, strontium ranelate 2 g per day and zoledronic acid 5 mg per annum.</p> <p>Details of prior anti-resorptive therapy, fracture history including the date(s), site(s), the symptoms associated with the fracture(s) which developed after at least 12 months continuous anti-resorptive therapy and the score of the qualifying BMD measurement must be provided at the time of application.</p> <p><b>Note</b> Details of accepted toxicities including severity can be found on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>.</p> <p><b>Note</b> No increase in the maximum quantity or number of units may be authorised.</p> <p><b>Note</b> No increase in the maximum number of repeats may be authorised.</p> <p><b>Note</b> Special Pricing Arrangements apply.</p> <p><b>Authority required</b> Severe established osteoporosis Treatment Phase: Continuing treatment</p> <p><b>The Clinical criteria is:</b> Patient must have previously been issued with an authority prescription for this drug,</p> <p><b>AND the Clinical criteria is:</b> The treatment must not exceed a lifetime maximum of 18 months therapy.</p> <p><b>Note</b> Up to a maximum of 18 pens will be reimbursed through the PBS.</p> <p><b>Note</b> No increase in the maximum quantity or number of units may be authorised.</p> <p><b>Note</b> No increase in the maximum number of repeats may be authorised.</p> <p><b>Note</b> Special Pricing Arrangements apply.</p>						
9411H	teriparatide 20 microgram/dose injection, 1 x 2.4 mL cartridge	1	5	..	438.58	36.90	Forteo LY

### TRANDOLAPRIL + VERAPAMIL

#### **Restricted benefit**

Hypertension

#### **The Clinical criteria is:**

The treatment must not be for the initiation of anti-hypertensive therapy,

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<b>AND the Clinical criteria is:</b>								
The condition must be inadequately controlled with an ACE inhibitor; OR								
The condition must be inadequately controlled with verapamil.								
<b>Caution</b>								
The myocardial depressant effects of verapamil hydrochloride and of beta-blocking drugs are additive.								
<b>Caution</b>								
Use of ACE inhibitors during pregnancy is contraindicated since these drugs have been associated with foetal death in utero.								
9387C NP	trandolapril 2 mg + verapamil hydrochloride 180 mg tablet: modified release, 28 tablets	1	5	..	19.31	20.44	Tarka 2/180	AB
2857J NP	trandolapril 4 mg + verapamil hydrochloride 240 mg tablet: modified release, 28 tablets	1	5	..	26.90	28.03	Tarka 4/240	AB
<b>VALSARTAN + HYDROCHLOROTHIAZIDE</b>								
<b>Restricted benefit</b>								
Hypertension								
<b>The Clinical criteria is:</b>								
The treatment must not be for the initiation of anti-hypertensive therapy,								
<b>AND the Clinical criteria is:</b>								
The condition must be inadequately controlled with an angiotensin II antagonist; OR								
The condition must be inadequately controlled with a thiazide diuretic.								
<b>Note</b>								
No applications for increased maximum quantities and/or repeats will be authorised for the tablets containing 320 mg valsartan.								
9481B NP	valsartan 320 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	25.81	26.94	Co-Diovan 320/12.5	NV
9482C NP	valsartan 320 mg + hydrochlorothiazide 25 mg tablet, 28	1	5	..	27.88	29.01	Co-Diovan 320/25	NV
<b>VALSARTAN + HYDROCHLOROTHIAZIDE</b>								
<b>Restricted benefit</b>								
Hypertension								
<b>The Clinical criteria is:</b>								
The treatment must not be for the initiation of anti-hypertensive therapy,								
<b>AND the Clinical criteria is:</b>								
The condition must be inadequately controlled with an angiotensin II antagonist; OR								
The condition must be inadequately controlled with a thiazide diuretic.								
9372G NP	valsartan 80 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	19.12	20.25	Co-Diovan 80/12.5	NV
9373H NP	valsartan 160 mg + hydrochlorothiazide 12.5 mg tablet, 28	1	5	..	22.06	23.19	Co-Diovan 160/12.5	NV
9374J NP	valsartan 160 mg + hydrochlorothiazide 25 mg tablet, 28	1	5	..	24.13	25.26	Co-Diovan 160/25	NV

## HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed		Brand Name and Manufacturer	
					Price for Max. Qty \$			
<b>CLOZAPINE</b>								
<b><u>Authority required (STREAMLINED)</u></b>								
<b>4411</b>								
Schizophrenia								
<b>The Clinical criteria is:</b>								
Patient must be non-responsive to other neuroleptic agents; OR								
Patient must be intolerant of other neuroleptic agents.								
A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.								
<b><u>Note</u></b>								
Patients receiving clozapine under the PBS listing must be registered in a clozapine patient monitoring program; Novartis Clozaril Patient Monitoring System (CPMSplus) or Clopineconnect.								
5628F	clozapine 25 mg tablet, 100	2	..	..	*89.18	<sup>a</sup>	Clopine 25	HH
5626D	clozapine 50 mg tablet, 100	2	..	..	*178.36	<sup>a</sup>	Clozaril 25 Clopine 50	NV HH
5629G	clozapine 100 mg tablet, 100	2	..	..	*334.40	<sup>a</sup>	Clopine 100	HH
5627E	clozapine 200 mg tablet, 100	2	..	..	*668.82	<sup>a</sup>	Clozaril 100 Clopine 200	NV HH
5630H	clozapine 50 mg/mL oral liquid, 100 mL	1	..	..	135.00		Clopine Suspension	HH

## HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
<b>CLOZAPINE</b>						
<b><u>Authority required</u></b>						
Schizophrenia						
<b>The Clinical criteria is:</b>						
Patient must be non-responsive to other neuroleptic agents; OR						
Patient must be intolerant of other neuroleptic agents.						
A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.						
<b><u>Note</u></b>						
Patients receiving clozapine under the PBS listing must be registered in a clozapine patient monitoring program; Novartis Clozaril Patient Monitoring System (CPMSplus) or Clopineconnect.						
6101D	clozapine 25 mg tablet, 100	2	..	..	*99.81	<sup>a</sup> Clopine 25 HH
6417R	clozapine 50 mg tablet, 100	2	..	..	*192.13	<sup>a</sup> Clozaril 25 NV Clopine 50 HH
6102E	clozapine 100 mg tablet, 100	2	..	..	*354.41	<sup>a</sup> Clopine 100 HH
6418T	clozapine 200 mg tablet, 100	2	..	..	*702.21	<sup>a</sup> Clozaril 100 NV Clopine 200 HH
9632Y	clozapine 50 mg/mL oral liquid, 100 mL	1	..	..	147.03	Clopine Suspension HH

## REPATRIATION PHARMACEUTICAL BENEFITS

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

#### Authority required

Males with vasculogenic, psychogenic or neurogenic erectile dysfunction

#### The Clinical criteria is:

Patient must have a specific accepted war-caused or service-related disability.

Authorisation will not be given for any additional prescriptions within 6 months or for any increased quantities or repeats.

10031Y	alprostadil 10 microgram injection [1 x 10 microgram vial] (&) inert substance diluent [1 syringe], 1 pack	6	3	..	*105.69	6.00	Caverject	PF
10030X	alprostadil 20 microgram injection [1 x 20 microgram vial] (&) inert substance diluent [1 syringe], 1 pack	6	3	..	*133.05	6.00	Caverject	PF

### DRESSING FOAM WITH SILICONE

#### Note

Smith & Nephew products are distributed via the three major wholesalers, API, Sigma and Symbion. To best ensure product availability at RPBS agreed prices, please order from one of these suppliers. In the event that your preferred wholesaler cannot supply, please contact Smith & Nephew Customer Service on 13 13 60. Smith & Nephew cannot ensure RPBS agreed pricing from distributors other than those aforementioned.

10017F	dressing foam with silicone 10.3 cm x 10.3 cm dressing, 10	‡1	..	..	55.27	6.00	Allevyn Life 66801067	SN
10029W	dressing foam with silicone 12.9 cm x 12.9 cm dressing, 10	‡1	..	..	79.48	6.00	Allevyn Life 66801068	SN
10021K	dressing foam with silicone 21 cm x 21 cm dressing, 10	‡1	..	..	220.62	6.00	Allevyn Life 66801070	SN
10023M	dressing foam with silicone 15.4 cm x 15.4 cm dressing, 10	‡1	..	..	110.46	6.00	Allevyn Life 66801069	SN