



**Australian Government**

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**Department of Health**

**SCHEDULE OF PHARMACEUTICAL  
BENEFITS**

**SUMMARY OF CHANGES**

**EFFECTIVE 1 August 2014**

## PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 August 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 August 2014 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.76
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.80
	Allowable additional patient charge*	\$4.19
Additional Fees (for safety net prices):	Ready-prepared	\$1.15
	Extemporaneously-prepared	\$1.50
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

10124W	<b>Acidinium</b> , acildinium bromide 400 microgram/actuation inhalation: powder for, 60 actuations ( <i>Bretaris Genuair</i> )
10119N	<b>Betaine</b> , betaine 1 g/g oral liquid: powder for, 180 g ( <i>Cystadane</i> )
10112F	<b>Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate</b> , macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL ( <i>Movicol Liquid</i> ) ( <b>Palliative Care</b> )
10127B	<b>Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate</b> , macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL ( <i>Movicol Liquid</i> ) ( <b>Palliative Care</b> )
10126Y	<b>Macrogol-3350 + Sodium Chloride + Potassium Chloride + Bicarbonate</b> , macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL ( <i>Movicol Liquid</i> )
10128C	<b>Saxagliptin</b> , saxagliptin 2.5 mg tablet, 28 ( <i>Onglyza</i> )
10113G	<b>Ticarcillin + Clavulanic Acid</b> , ticarcillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial ( <i>Timentin</i> )
10125X	<b>Ticarcillin + Clavulanic Acid</b> , ticarcillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial ( <i>Timentin</i> )

#### Addition – Brand

3116B	<i>Cal-500, PP</i> – <b>Calcium</b> , CALCIUM Tablet (chewable) 500 mg (as carbonate), 60
8361C	<i>Capecitabine Actavis, GN</i> – <b>Capecitabine</b> , capecitabine 150 mg tablet, 60
8361C	<i>Capecitabine Alphapharm, AF</i> – <b>Capecitabine</b> , capecitabine 150 mg tablet, 60
8361C	<i>Capecitabine Sandoz, SZ</i> – <b>Capecitabine</b> , capecitabine 150 mg tablet, 60
8361C	<i>Capecitabine-DRLA, RZ</i> – <b>Capecitabine</b> , capecitabine 150 mg tablet, 60
8362D	<i>Capecitabine Actavis, GN</i> – <b>Capecitabine</b> , capecitabine 500 mg tablet, 120
8362D	<i>Capecitabine Alphapharm, AF</i> – <b>Capecitabine</b> , capecitabine 500 mg tablet, 120
8362D	<i>Capecitabine Apotex, TX</i> – <b>Capecitabine</b> , capecitabine 500 mg tablet, 120
8362D	<i>Capecitabine GH, GQ</i> – <b>Capecitabine</b> , capecitabine 500 mg tablet, 120
8362D	<i>Capecitabine Sandoz, SZ</i> – <b>Capecitabine</b> , capecitabine 500 mg tablet, 120
8362D	<i>Capecitabine-DRLA, RZ</i> – <b>Capecitabine</b> , capecitabine 500 mg tablet, 120
1147J	<i>AP0-Captopril, TX</i> – <b>Captopril</b> , captopril 12.5 mg tablet, 90
1148K	<i>AP0-Captopril, TX</i> – <b>Captopril</b> , captopril 25 mg tablet, 90
1149L	<i>AP0-Captopril, TX</i> – <b>Captopril</b> , captopril 50 mg tablet, 90
1270W	<i>Cyrotone, ER</i> – <b>Cyproterone</b> , cyproterone acetate 50 mg tablet, 50
1370D	<i>Malean, FM</i> – <b>Enalapril</b> , enalapril maleate 5 mg tablet, 30
1368B	<i>Malean, FM</i> – <b>Enalapril</b> , enalapril maleate 10 mg tablet, 30
1369C	<i>Malean, FM</i> – <b>Enalapril</b> , enalapril maleate 20 mg tablet, 30
8886Q	<i>Esomeprazole RBX, RA</i> – <b>Esomeprazole</b> , esomeprazole 20 mg tablet: enteric, 30 tablets
8600P	<i>Esomeprazole RBX, RA</i> – <b>Esomeprazole</b> , esomeprazole 20 mg tablet: enteric, 30 tablets
8601Q	<i>Esomeprazole RBX, RA</i> – <b>Esomeprazole</b> , esomeprazole 40 mg tablet: enteric, 30 tablets
3401B	<i>Esomeprazole RBX, RA</i> – <b>Esomeprazole</b> , esomeprazole 40 mg tablet: enteric, 30 tablets
8246B	<i>Irprestan 75, ZP</i> – <b>Irbesartan</b> , irbesartan 75 mg tablet, 30
8247C	<i>Irprestan 150, ZP</i> – <b>Irbesartan</b> , irbesartan 150 mg tablet, 30
8248D	<i>Irprestan 300, ZP</i> – <b>Irbesartan</b> , irbesartan 300 mg tablet, 30
8404H	<i>Irbesartan HCT Actavis 150/12.5, UA</i> – <b>Irbesartan + Hydrochlorothiazide</b> , irbesartan 150 mg + hydrochlorothiazide 12.5 mg tablet, 30
2136K	<i>Irbesartan HCT Actavis 300/25, UA</i> – <b>Irbesartan + Hydrochlorothiazide</b> , irbesartan 300 mg + hydrochlorothiazide 25 mg tablet, 30
8654L	<i>Levi 250, FM</i> – <b>Levetiracetam</b> , levetiracetam 250 mg tablet, 60
8655M	<i>Levi 500, FM</i> – <b>Levetiracetam</b> , levetiracetam 500 mg tablet, 60
8656N	<i>Levi 1000, FM</i> – <b>Levetiracetam</b> , levetiracetam 1 g tablet, 60
5400F	<i>Aspen Methadone Syrup, QA</i> – <b>Methadone</b> , methadone hydrochloride 5 mg/mL oral liquid, 200 mL ( <b>Palliative Care</b> )
5399E	<i>Aspen Methadone Syrup, QA</i> – <b>Methadone</b> , methadone hydrochloride 5 mg/mL oral liquid, 200 mL ( <b>Palliative Care</b> )
8732N	<i>Metrol-XL 23.75, QA</i> – <b>Metoprolol Succinate</b> , METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15
8732N	<i>Minax XL, AF</i> – <b>Metoprolol Succinate</b> , METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15
8733P	<i>Metrol-XL 47.5, QA</i> – <b>Metoprolol Succinate</b> , METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30
8733P	<i>Minax XL, AF</i> – <b>Metoprolol Succinate</b> , METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30
8734Q	<i>Metrol-XL 95, QA</i> – <b>Metoprolol Succinate</b> , METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30
8734Q	<i>Minax XL, AF</i> – <b>Metoprolol Succinate</b> , METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30
8735R	<i>Metrol-XL 190, QA</i> – <b>Metoprolol Succinate</b> , METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30
8735R	<i>Minax XL, AF</i> – <b>Metoprolol Succinate</b> , METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30
8456C	<i>Quetia 25, FM</i> – <b>Quetiapine</b> , quetiapine 25 mg tablet, 60

8457D	<i>Quetia 100, FM</i> – <b>Quetiapine</b> , quetiapine 100 mg tablet, 90
8458E	<i>Quetia 200, FM</i> – <b>Quetiapine</b> , quetiapine 200 mg tablet, 60
8580N	<i>Quetia 300, FM</i> – <b>Quetiapine</b> , quetiapine 300 mg tablet, 60
8646C	<i>Pharmacor Tacrolimus 0.5, CR</i> – <b>Tacrolimus</b> , tacrolimus 500 microgram capsule, 100
8647D	<i>Pharmacor Tacrolimus 1, CR</i> – <b>Tacrolimus</b> , tacrolimus 1 mg capsule, 100
8648E	<i>Pharmacor Tacrolimus 5, CR</i> – <b>Tacrolimus</b> , tacrolimus 5 mg capsule, 50
8350L	<i>Tirofiban AC, GN</i> – <b>Tirofiban</b> , tirofiban 12.5 mg/50 mL injection, 1 x 50 mL vial

### Addition – Equivalence Indicator

3116B	<i>Cal-Sup, IA</i> – <b>Calcium</b> , CALCIUM Tablet (chewable) 500 mg (as carbonate), 60
8361C	<i>Xeloda, RO</i> – <b>Capecitabine</b> , capecitabine 150 mg tablet, 60
8362D	<i>Xeloda, RO</i> – <b>Capecitabine</b> , capecitabine 500 mg tablet, 120
8600P	<i>Nexium, AP</i> – <b>Esomeprazole</b> , esomeprazole 20 mg tablet: enteric, 30 tablets
8886Q	<i>Nexium, AP</i> – <b>Esomeprazole</b> , esomeprazole 20 mg tablet: enteric, 30 tablets
3401B	<i>Nexium, AP</i> – <b>Esomeprazole</b> , esomeprazole 40 mg tablet: enteric, 30 tablets
8601Q	<i>Nexium, AP</i> – <b>Esomeprazole</b> , esomeprazole 40 mg tablet: enteric, 30 tablets
8732N	<i>Toprol-XL 23.75, AP</i> – <b>Metoprolol Succinate</b> , METOPROLOL SUCCINATE Tablet 23.75 mg (controlled release), 15
8733P	<i>Toprol-XL 47.5, AP</i> – <b>Metoprolol Succinate</b> , METOPROLOL SUCCINATE Tablet 47.5 mg (controlled release), 30
8734Q	<i>Toprol-XL 95, AP</i> – <b>Metoprolol Succinate</b> , METOPROLOL SUCCINATE Tablet 95 mg (controlled release), 30
8735R	<i>Toprol-XL 190, AP</i> – <b>Metoprolol Succinate</b> , METOPROLOL SUCCINATE Tablet 190 mg (controlled release), 30
8350L	<i>Aggrastat, AS</i> – <b>Tirofiban</b> , tirofiban 12.5 mg/50 mL injection, 1 x 50 mL vial

### Deletions

#### Deletion – Item

9166K	<b>Erlotinib</b> , erlotinib 25 mg tablet, 30 ( <i>Tarceva</i> )
9167L	<b>Erlotinib</b> , erlotinib 100 mg tablet, 30 ( <i>Tarceva</i> )
9168M	<b>Erlotinib</b> , erlotinib 150 mg tablet, 30 ( <i>Tarceva</i> )
5154G	<b>Metronidazole</b> , metronidazole 500 mg/100 mL (0.5%) injection, 1 x 100 mL bag ( <i>Baxter Healthcare Pty Ltd</i> )
1638F	<b>Metronidazole</b> , metronidazole 500 mg/100 mL (0.5%) injection, 1 x 100 mL bag ( <i>Baxter Healthcare Pty Ltd</i> )
5494E	<b>Telmisartan</b> , telmisartan 40 mg tablet, 28 ( <i>Micardis</i> )
5495F	<b>Telmisartan</b> , telmisartan 80 mg tablet, 28 ( <i>Micardis</i> )
5230G	<b>Ticarcillin + Clavulanic Acid</b> , ticarcillin 3 g + clavulanic acid 100 mg injection, 10 x 3.1 g vials ( <i>Timentin</i> )
2179Q	<b>Ticarcillin + Clavulanic Acid</b> , ticarcillin 3 g + clavulanic acid 100 mg injection, 10 x 3.1 g vials ( <i>Timentin</i> )

#### Deletion – Brand

2130D	<i>Alprazolam Sandoz, SZ</i> – <b>Alprazolam</b> , alprazolam 250 microgram tablet, 50
2131E	<i>Alprazolam Sandoz, SZ</i> – <b>Alprazolam</b> , alprazolam 500 microgram tablet, 50
2132F	<i>Alprazolam Sandoz, SZ</i> – <b>Alprazolam</b> , alprazolam 1 mg tablet, 50
8118G	<i>Alprazolam Sandoz, SZ</i> – <b>Alprazolam</b> , alprazolam 2 mg tablet, 50
2344J	<i>Amiodarone Sandoz, SZ</i> – <b>Amiodarone</b> , amiodarone hydrochloride 100 mg tablet, 30
5400F	<i>Sigma Methadone Syrup, QA</i> – <b>Methadone</b> , methadone hydrochloride 5 mg/mL oral liquid, 200 mL ( <b>Palliative Care</b> )
5399E	<i>Sigma Methadone Syrup, QA</i> – <b>Methadone</b> , methadone hydrochloride 5 mg/mL oral liquid, 200 mL ( <b>Palliative Care</b> )
1967M	<i>Locilan 28 Day, FZ</i> – <b>Norethisterone</b> , norethisterone 350 microgram tablet, 112 [4 x 28]
3130R	<i>Vycin IV, GN</i> – <b>Vancomycin</b> , vancomycin 500 mg injection, 1 x 500 mg vial
3323X	<i>Vycin IV, GN</i> – <b>Vancomycin</b> , vancomycin 500 mg injection, 1 x 500 mg vial
3131T	<i>Vycin IV, GN</i> – <b>Vancomycin</b> , vancomycin 500 mg injection, 1 x 500 mg vial

#### Deletion – Equivalence Indicator

1967M	<i>Noriday 28 Day, PF</i> – <b>Norethisterone</b> , norethisterone 350 microgram tablet, 112 [4 x 28]
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### Alterations

#### Alteration – Restriction

Note: Items which are Streamlined drugs have had a code change.

9092M	<b>Atomoxetine</b> , atomoxetine 10 mg capsule, 28 ( <i>Strattera</i> )
9093N	<b>Atomoxetine</b> , atomoxetine 18 mg capsule, 28 ( <i>Strattera</i> )
9094P	<b>Atomoxetine</b> , atomoxetine 25 mg capsule, 28 ( <i>Strattera</i> )
9095Q	<b>Atomoxetine</b> , atomoxetine 40 mg capsule, 28 ( <i>Strattera</i> )
9096R	<b>Atomoxetine</b> , atomoxetine 60 mg capsule, 28 ( <i>Strattera</i> )
9289X	<b>Atomoxetine</b> , atomoxetine 80 mg capsule, 28 ( <i>Strattera</i> )
9290Y	<b>Atomoxetine</b> , atomoxetine 100 mg capsule, 28 ( <i>Strattera</i> )
3116B	<b>Calcium</b> , CALCIUM Tablet (chewable) 500 mg (as carbonate), 60 ( <i>Cal-500, Cal-Sup</i> )
3117C	<b>Calcium</b> , CALCIUM Tablet 600 mg (as carbonate), 240 ( <i>Calci-Tab 600</i> )

10028T	<b>Erlotinib</b> , erlotinib 25 mg tablet, 30 ( <i>Tarceva</i> )
10019H	<b>Erlotinib</b> , erlotinib 100 mg tablet, 30 ( <i>Tarceva</i> )
10025P	<b>Erlotinib</b> , erlotinib 150 mg tablet, 30 ( <i>Tarceva</i> )
8612G	<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 ( <i>APO-MACROGOL plus ELECTROLYTES, LaxaCon, lax-sachets, Molaxole, Movicol</i> )
5390Q	<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 ( <i>APO-MACROGOL plus ELECTROLYTES, LaxaCon, lax-sachets, Molaxole, Movicol</i> )( <b>Palliative Care</b> )
5389P	<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 ( <i>APO-MACROGOL plus ELECTROLYTES, LaxaCon, lax-sachets, Molaxole, Movicol</i> )( <b>Palliative Care</b> )
2277W	<b>Metronidazole</b> , metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags ( <i>Metronidazole-Claris</i> )
2298Y	<b>Metronidazole</b> , metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags ( <i>Metronidazole-Claris</i> )
1821W	<b>Metronidazole</b> , metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags ( <i>DBL Metronidazole Intravenous Infusion, Metronidazole Sandoz IV</i> )
1832K	<b>Metronidazole</b> , metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags ( <i>DBL Metronidazole Intravenous Infusion, Metronidazole Sandoz IV</i> )

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

9092M	<i>Strattera, LY– Atomoxetine</i> , atomoxetine 10 mg capsule, 28
9093N	<i>Strattera, LY– Atomoxetine</i> , atomoxetine 18 mg capsule, 28
9094P	<i>Strattera, LY– Atomoxetine</i> , atomoxetine 25 mg capsule, 28
9095Q	<i>Strattera, LY– Atomoxetine</i> , atomoxetine 40 mg capsule, 28
9096R	<i>Strattera, LY– Atomoxetine</i> , atomoxetine 60 mg capsule, 28
9289X	<i>Strattera, LY– Atomoxetine</i> , atomoxetine 80 mg capsule, 28
9290Y	<i>Strattera, LY– Atomoxetine</i> , atomoxetine 100 mg capsule, 28

### Alteration – Manufacturer's Code

8775W	<i>Arixtra, AS– Fondaparinux</i> , FONDAPARINUX SODIUM Injection 2.5 mg in 0.5 mL single dose pre-filled syringe, 2	From: GK	To: AS
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### Advance Notices

#### Advance Notices – Deletion of Item

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

5005K	<b>Glucose</b> , glucose 5% (25 g/500 mL) injection, 1 x 500 mL bag ( <i>Fresenius Kabi Australia Pty Limited</i> )
9444C	<b>Glucose</b> , glucose 5% (25 g/500 mL) injection, 1 x 500 mL bag ( <i>Fresenius Kabi Australia Pty Limited</i> )
9445D	<b>Glucose</b> , glucose 10% (50 g/500 mL) injection, 1 x 500 mL bag ( <i>Fresenius Kabi Australia Pty Limited</i> )
9474P	<b>Glucose</b> , glucose 5% (12.5 g/250 mL) injection, 1 x 250 mL bag ( <i>Glucose 5% Freeflex</i> )
9416N	<b>Lactate + Sodium Chloride + Potassium Chloride + Calcium Chloride Dihydrate</b> , 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 ( <i>Fresenius Kabi Australia Pty Limited</i> )
8272J	<b>Omeprazole (&amp;) Clarithromycin (&amp;) Amoxicillin</b> , omeprazole 20 mg capsule [14 capsules] (&) clarithromycin 500 mg tablet [14 tablets] (&) amoxicillin 500 mg capsule [28 capsules], 1 pack ( <i>Probitor Hp7</i> )
2942W	<b>Oxprenolol</b> , oxprenolol hydrochloride 20 mg tablet, 100 ( <i>Corbeton 20</i> )
5021G	<b>Sodium Chloride</b> , sodium chloride 0.9% (4.5 g/500 mL) injection, 1 x 500 mL bag ( <i>Fresenius Kabi Australia Pty Limited</i> )
9392H	<b>Sodium Chloride</b> , sodium chloride 0.9% (4.5 g/500 mL) injection, 1 x 500 mL bag ( <i>Fresenius Kabi Australia Pty Limited</i> )
9473N	<b>Sodium Chloride</b> , sodium chloride 0.9% (2.25 g/250 mL) injection, 1 x 250 mL bag ( <i>Sodium Chloride 0.9% Freeflex</i> )
8099G	<b>Testosterone</b> , testosterone 200 mg implant, 1 ( <i>Merck Sharp &amp; Dohme (Australia) Pty Ltd</i> )
8098F	<b>Testosterone</b> , testosterone 100 mg implant, 1 ( <i>Merck Sharp &amp; Dohme (Australia) Pty Ltd</i> )

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

2776D	<b>Ethinylloestradiol + Norethisterone</b> , ethinylloestradiol 35 microgram + norethisterone 500 microgram tablet [48] (&) ethinylloestradiol 35 microgram + norethisterone 1 mg tablet [36] (&) inert substance tablet [28], 112 [4 x 28] ( <i>Improvil 28 Day</i> )
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## SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

### Additions

#### Addition – Item

10130E	<b>Epoprostenol</b> , epoprostenol 500 microgram injection, 1 x 500 microgram vial ( <i>Veletri</i> ) <b>(Public)</b>
10111E	<b>Epoprostenol</b> , epoprostenol 500 microgram injection, 1 x 500 microgram vial ( <i>Veletri</i> ) <b>(Private)</b>
10117L	<b>Epoprostenol</b> , epoprostenol 1.5 mg injection, 1 x 1.5 mg vial ( <i>Veletri</i> ) <b>(Public)</b>
10129D	<b>Epoprostenol</b> , epoprostenol 1.5 mg injection, 1 x 1.5 mg vial ( <i>Veletri</i> ) <b>(Private)</b>
10118M	<b>Omalizumab</b> , omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe ( <i>Xolair</i> ) <b>(Public)</b>
10110D	<b>Omalizumab</b> , omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe ( <i>Xolair</i> ) <b>(Private)</b>
10109C	<b>Omalizumab</b> , omalizumab 150 mg/mL injection, 1 x 1 mL syringe ( <i>Xolair</i> ) <b>(Public)</b>
10122R	<b>Omalizumab</b> , omalizumab 150 mg/mL injection, 1 x 1 mL syringe ( <i>Xolair</i> ) <b>(Private)</b>

#### Addition – Brand

9547L	<i>APO-Sildenafil PHT, TX</i> – <b>Sildenafil</b> , sildenafil 20 mg tablet, 90 <b>(Public)</b>
9605M	<i>APO-Sildenafil PHT, TX</i> – <b>Sildenafil</b> , sildenafil 20 mg tablet, 90 <b>(Private)</b>
9547L	<i>Sildenafil Sandoz PHT 20, SZ</i> – <b>Sildenafil</b> , sildenafil 20 mg tablet, 90 <b>(Public)</b>
9605M	<i>Sildenafil Sandoz PHT 20, SZ</i> – <b>Sildenafil</b> , sildenafil 20 mg tablet, 90 <b>(Private)</b>
9558C	<i>Pharmacor Tacrolimus 0.5, CR</i> – <b>Tacrolimus</b> , tacrolimus 500 microgram capsule, 100 <b>(Public)</b>
6328C	<i>Pharmacor Tacrolimus 0.5, CR</i> – <b>Tacrolimus</b> , tacrolimus 500 microgram capsule, 100 <b>(Private)</b>
9560E	<i>Pharmacor Tacrolimus 1, CR</i> – <b>Tacrolimus</b> , tacrolimus 1 mg capsule, 100 <b>(Public)</b>
6216E	<i>Pharmacor Tacrolimus 1, CR</i> – <b>Tacrolimus</b> , tacrolimus 1 mg capsule, 100 <b>(Private)</b>
9561F	<i>Pharmacor Tacrolimus 5, CR</i> – <b>Tacrolimus</b> , tacrolimus 5 mg capsule, 50 <b>(Public)</b>
6217F	<i>Pharmacor Tacrolimus 5, CR</i> – <b>Tacrolimus</b> , tacrolimus 5 mg capsule, 50 <b>(Private)</b>

#### Addition – Equivalence Indicator

5042J	<i>Flolan Kit, GK</i> – <b>Epoprostenol</b> , EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1 <b>(Private)</b>
5035B	<i>Flolan Kit, GK</i> – <b>Epoprostenol</b> , EPOPROSTENOL SODIUM Powder for I.V. infusion 1.5 mg (base) infusion administration set, 1 <b>(Public)</b>
5036C	<i>Flolan Kit, GK</i> – <b>Epoprostenol</b> , EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1 <b>(Private)</b>
5030R	<i>Flolan Kit, GK</i> – <b>Epoprostenol</b> , EPOPROSTENOL SODIUM Powder for I.V. infusion 500 micrograms (base) infusion administration set, 1 <b>(Public)</b>
9605M	<i>Revatio, PF</i> – <b>Sildenafil</b> , sildenafil 20 mg tablet, 90 <b>(Private)</b>
9547L	<i>Revatio, PF</i> – <b>Sildenafil</b> , sildenafil 20 mg tablet, 90 <b>(Public)</b>

### Advance Notices

#### Advance Notices – Deletion of Item

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

5821J	<b>Darunavir</b> , darunavir 400 mg tablet, 60 ( <i>Prezista</i> ) <b>(Public)</b>
5823L	<b>Darunavir</b> , darunavir 400 mg tablet, 60 ( <i>Prezista</i> ) <b>(Private)</b>

## SECTION 100 – IVF/GIFT TREATMENT

### Additions

#### Addition – Item

10116K	<b>Progesterone</b> , progesterone 100 mg pessary, 21 ( <i>Endometrin</i> )
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### Alterations

#### Alteration – Restriction

5816D	<b>Corifollitropin Alfa</b> , corifollitropin alfa 100 microgram/0.5 mL injection, 1 x 0.5 mL syringe ( <i>Elonva</i> )
9608Q	<b>Progesterone</b> , progesterone 100 mg pessary, 15 ( <i>Oripro</i> )
9609R	<b>Progesterone</b> , progesterone 200 mg pessary, 15 ( <i>Oripro</i> )
6366C	<b>Progesterone</b> , progesterone 8% vaginal gel, 15 applications ( <i>Crinone 8%</i> )

## SECTION 100 – OPIATE DEPENDENCE TREATMENT PROGRAM

### Additions

#### Addition – Brand

- 6171T *Aspen Methadone Syrup, QA – Methadone*, methadone hydrochloride 5 mg/mL oral liquid, 200 mL  
 6172W *Aspen Methadone Syrup, QA – Methadone*, methadone hydrochloride 5 mg/mL oral liquid, 1000 mL

### Deletions

#### Deletion – Brand

- 6171T *Sigma Methadone Syrup, QA – Methadone*, methadone hydrochloride 5 mg/mL oral liquid, 200 mL  
 6172W *Sigma Methadone Syrup, QA – Methadone*, methadone hydrochloride 5 mg/mL oral liquid, 1000 mL

## REPATRIATION PHARMACEUTICAL BENEFITS

### Additions

#### Addition – Brand

- 4698G *Aquacel 403770, CC – Dressing Hydrofibre Alternate To Alginates*, dressing hydrofibre alternate to alginates 2 g (30 cm) rope, 5 x 2 g

### Deletions

#### Deletion – Item

- 4649Q **Dressing Hydrofibre Alternate To Alginates**, dressing hydrofibre alternate to alginates 10 cm x 10 cm dressing, 10 (*Aquacel 177902*)  
 4922C **Dressing Hydrofibre Alternate To Alginates**, dressing hydrofibre alternate to alginates 15 cm x 15 cm dressing, 5 (*Aquacel 177903*)  
 4416K **Psyllium Husk Powder + Starch-maize High Amylose**, psyllium husk powder 375 mg/g + starch-maize high amylose 375 mg/g oral liquid: powder for, 440 g (*Nucloxx*)  
 4482X **Triamcinolone + Neomycin Sulfate + Gramicidin + Nystatin**, triamcinolone acetonide 0.1% + neomycin sulfate 0.25% + gramicidin 0.025% + nystatin 100 000 international units/g ointment, 15 g (*Kenacomb*)

#### Deletion – Brand

- 4698G *Aquacel 177904, CC – Dressing Hydrofibre Alternate To Alginates*, dressing hydrofibre alternate to alginates 2 g (30 cm) rope, 5 x 2 g

#### Deletion – Equivalence Indicator

- 4010C *Aporyl, TX – Amorolfine*, amorolfine 5% application, 5 mL  
 4010C *Loceryl, GA – Amorolfine*, amorolfine 5% application, 5 mL

## 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>ACOLIDINIUM</b>								
<b><u>Restricted benefit</u></b>								
Chronic obstructive pulmonary disease (COPD)								
10124W NP	acclidinium bromide 400 microgram/actuation inhalation: powder for, 60 actuations	1	5	..	62.73	36.90	Bretaris Genuair	FK
<b>ATOMOXETINE</b>								
<b><u>Authority required (STREAMLINED)</u></b>								
4591								
Attention deficit hyperactivity disorder								
Treatment Phase: Initial treatment								
<b>Clinical criteria:</b>								
The condition must be or have been diagnosed by a paediatrician or psychiatrist according to the DSM-5 criteria,								
<b>AND</b>								
Patient must have a contraindication to dexamphetamine or methylphenidate as specified in TGA-approved product information; OR								
Patient must have a comorbid mood disorder that has developed or worsened as a result of dexamphetamine or methylphenidate treatment and is of a severity necessitating treatment withdrawal; OR								
Patient must be at an unacceptable medical risk of a severity necessitating permanent stimulant treatment withdrawal if given a stimulant treatment with another agent; OR								
Patient must have experienced adverse reactions of a severity necessitating permanent treatment withdrawal following treatment with dexamphetamine and treatment with methylphenidate (not simultaneously).								
<b>Population criteria:</b>								
Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.								
<b><u>Authority required (STREAMLINED)</u></b>								
4578								
Attention deficit hyperactivity disorder								
Treatment Phase: Continuing treatment								
<b>Clinical criteria:</b>								
Patient must have previously been issued with an authority prescription for this drug.								
<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.								
9092M	atomoxetine 10 mg capsule, 28	2	5	..	*221.52	36.90	Strattera	LY
9093N	atomoxetine 18 mg capsule, 28	2	5	..	*221.52	36.90	Strattera	LY
9094P	atomoxetine 25 mg capsule, 28	2	5	..	*221.52	36.90	Strattera	LY
9095Q	atomoxetine 40 mg capsule, 28	2	5	..	*221.52	36.90	Strattera	LY
9096R	atomoxetine 60 mg capsule, 28	2	5	..	*221.52	36.90	Strattera	LY
9289X	atomoxetine 80 mg capsule, 28	1	5	..	147.45	36.90	Strattera	LY
9290Y	atomoxetine 100 mg capsule, 28	1	5	..	147.45	36.90	Strattera	LY

### BETAINE

#### **Authority required**

Homocystinuria

#### **Clinical criteria:**

The treatment must be as adjunctive therapy to current standard care,

#### **AND**

The condition must be treated by or in consultation with a metabolic physician.

The name of the specialist 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	
10119N	betaine 1 g/g oral liquid: powder for, 180 g	†1	5	..	570.55	36.90	Cystadane	EU
<b>CALCIUM</b>								
<b><u>Authority required (STREAMLINED)</u></b>								
4586								
Hyperphosphataemia								
<b>Clinical criteria:</b>								
The condition must be associated with chronic renal failure.								
3116B NP	CALCIUM Tablet (chewable) 500 mg (as carbonate), 60	4	1	..	*29.24	30.39	<sup>a</sup> Cal-500	PP
3117C NP	CALCIUM Tablet 600 mg (as carbonate), 240	1	1	..	22.54	23.69	<sup>a</sup> Cal-Sup Calci-Tab 600	IA AE
<b>ERLOTINIB</b>								
<b><u>Authority required</u></b>								
Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)								
Treatment Phase: Continuing treatment								
<b>Clinical criteria:</b>								
The treatment must be as monotherapy,								
<b>AND</b>								
Patient must have previously been issued with an authority prescription for this drug prior to 1 August 2014,								
<b>AND</b>								
Patient must not have progressive disease.								
<b>Population criteria:</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.								
10028T	erlotinib 25 mg tablet, 30	1	3	..	355.07	36.90	Tarceva	RO
10019H	erlotinib 100 mg tablet, 30	1	3	..	1239.13	36.90	Tarceva	RO
10025P	erlotinib 150 mg tablet, 30	1	3	..	1514.10	36.90	Tarceva	RO

### MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE

#### **Restricted benefit**

Constipation

#### **Clinical criteria:**

Patient must have malignant neoplasia.

#### **Restricted benefit**

Constipation

#### **Clinical criteria:**

Patient must be paraplegic, quadriplegic or have severe neurogenic impairment of bowel function,

#### **AND**

The condition must be unresponsive to other oral therapies.

#### **Restricted benefit**

Constipation

#### **Clinical criteria:**

Patient must be receiving palliative care.

#### **Restricted benefit**

Chronic constipation

#### **Clinical criteria:**

The condition must be inadequately controlled with first line interventions such as bulk-forming agents.

#### **Restricted benefit**

Faecal impaction

## 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>Clinical criteria:</b>								
The condition must be inadequately controlled with first line interventions such as bulk-forming agents.								
10126Y NP	macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL	2	5	..	*25.60	26.75	Movicol Liquid	NE
8612G NP	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	1	5	..	20.89	22.04	<sup>a</sup> APO-MACROGOL plus ELECTROLYTES	TX
							<sup>a</sup> LaxaCon	GN
							<sup>a</sup> lax-sachets	AE
							<sup>a</sup> Molaxole	HM
							<sup>a</sup> Movicol	NE

### METRONIDAZOLE

#### **Restricted benefit**

Prophylaxis to prevent infection

#### **Clinical criteria:**

Patient must be undergoing large bowel surgery.

#### **Restricted benefit**

Acute anaerobic sepsis

#### **Treatment criteria:**

Must be treated in a hospital.

#### **Note**

Pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags and pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags are equivalent for the purposes of substitution.

2277W NP	metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags	2	..	..	*21.60	22.75	<sup>a</sup> Metronidazole-Claris	AE
1821W NP	metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags	1	..	..	21.60	22.75	<sup>a</sup> DBL Metronidazole Intravenous Infusion	HH
							<sup>a</sup> Metronidazole Sandoz IV	SZ

### METRONIDAZOLE

#### **Restricted benefit**

Acute anaerobic sepsis

#### **Treatment criteria:**

Must be treated in a hospital.

#### **Note**

Pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags and pharmaceutical benefits that have the form metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags are equivalent for the purposes of substitution.

2298Y DP	metronidazole 500 mg/100 mL (0.5%) injection, 5 x 100 mL bags	2	..	..	*21.60	22.75	<sup>a</sup> Metronidazole-Claris	AE
1832K DP	metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags	1	..	..	21.60	22.75	<sup>a</sup> DBL Metronidazole Intravenous Infusion	HH
							<sup>a</sup> Metronidazole Sandoz IV	SZ

## 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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### SAXAGLIPTIN

#### Authority required (STREAMLINED)

4520

Diabetes mellitus type 2

#### Clinical criteria:

The treatment must be in combination with metformin; OR

The treatment must be in combination with a sulfonylurea,

#### AND

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

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

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

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

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

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

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

#### Note

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

10128C NP	saxagliptin 2.5 mg tablet, 28	1	5	..	59.20	36.90	Onglyza	AP
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### TICARCILLIN + CLAVULANIC ACID

#### Restricted benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

#### Restricted benefit

Septicaemia, suspected

#### Restricted benefit

Septicaemia, proven

#### 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.

10113G NP	ticarcillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial	10	..	..	*163.76	36.90	Timentin	AS
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### TICARCILLIN + CLAVULANIC ACID

#### Restricted benefit

Infections where positive bacteriological evidence confirms that this antibiotic is an appropriate therapeutic agent

10125X DP	ticarcillin 3 g + clavulanic acid 100 mg injection, 1 x 3.1 g vial	10	..	..	*163.76	36.90	Timentin	AS
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## PREPARATIONS WHICH MAY BE PRESCRIBED FOR PATIENTS RECEIVING PALLIATIVE CARE

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>MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE</b>								
<b><u>Authority required (STREAMLINED)</u></b>								
4590								
Constipation								
Treatment Phase: Continuing treatment								
<b>Clinical criteria:</b>								
Patient must be receiving palliative care.								
<b>Note</b>								
Written or telephone authority applications for increased repeats may be approved where consultation with a palliative care specialist or service has occurred.								
10112F NP	macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL	2	..	..	*25.60	26.75	Movicol Liquid	NE
5390Q NP	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	2	..	..	*35.02	36.17	<sup>a</sup> APO-MACROGOL plus ELECTROLYTES	TX
							<sup>a</sup> LaxaCon	GN
							<sup>a</sup> lax-sachets	AE
							<sup>a</sup> Molaxole	HM
							<sup>a</sup> Movicol	NE
<b>MACROGOL-3350 + SODIUM CHLORIDE + POTASSIUM CHLORIDE + BICARBONATE</b>								
<b><u>Authority required (STREAMLINED)</u></b>								
4595								
Constipation								
Treatment Phase: Initial treatment								
<b>Clinical criteria:</b>								
Patient must be receiving palliative care,								
<b>AND</b>								
Patient must not receive more than 4 months treatment under this restriction.								
10127B NP	macrogol-3350 13.12 g/25 mL + sodium chloride 350.7 mg/25 mL + potassium chloride 46.6 mg/25 mL (0.63 mmol/25 mL potassium) + sodium bicarbonate 178.5 mg/25 mL oral liquid, 500 mL	2	3	..	*25.60	26.75	Movicol Liquid	NE
5389P NP	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	2	3	..	*35.02	36.17	<sup>a</sup> APO-MACROGOL plus ELECTROLYTES	TX
							<sup>a</sup> LaxaCon	GN
							<sup>a</sup> lax-sachets	AE
							<sup>a</sup> Molaxole	HM
							<sup>a</sup> Movicol	NE

## HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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### **EPOPROSTENOL**

#### **Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

- (a) WHO Functional Class IV primary pulmonary hypertension; OR
- (b) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [[www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)] which includes results from the 3 tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6MWT; and
- (3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

#### **Authority required**

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients with one of the following:

- (a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; OR
- (b) WHO Functional Class IV primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have received prior treatment with a PBS-subsidised PAH agent other than epoprostenol sodium; OR
- (c) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [[www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
- (3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
- (4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (5) for WHO Functional Class III patients, where this is the first application for epoprostenol sodium, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

#### **Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with epoprostenol sodium of patients who have received approval for initial PBS-subsidised treatment with epoprostenol sodium, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of epoprostenol sodium treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [[www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)] which includes results from the 3 tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and

## HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Brand Name and Manufacturer
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(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

### **Note**

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

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

### **Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

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	<p>(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or</p> <p>(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.</p> <p>2. Definition of WHO Functional Class III or IV disease severity.</p> <p>(a) WHO Functional Class III disease severity is defined as follows:</p> <p>Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.</p> <p>(b) WHO Functional Class IV disease severity is defined as follows:</p> <p>Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.</p> <p>3. Designated hospitals.</p> <p>Refer to the Medicare Australia website at <a href="http://www.medicareaustralia.gov.au">www.medicareaustralia.gov.au</a> for a list of designated hospitals.</p> <p>4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.</p> <p>(a) Initiation of treatment.</p> <p>The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.</p> <p>Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</p> <ol style="list-style-type: none"> <li>(1) RHC plus ECHO composite assessments;</li> <li>(2) RHC composite assessment plus 6MWT;</li> <li>(3) RHC composite assessment only.</li> </ol> <p>In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p> <ol style="list-style-type: none"> <li>(1) ECHO composite assessment plus 6MWT;</li> <li>(2) ECHO composite assessment only.</li> </ol> <p>Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.</p> <p>(b) Continuation of treatment.</p> <p>The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:</p> <ol style="list-style-type: none"> <li>(1) RHC plus ECHO composite assessments plus 6MWT;</li> <li>(2) RHC plus ECHO composite assessments;</li> <li>(3) RHC composite assessment plus 6MWT;</li> <li>(4) ECHO composite assessment plus 6MWT;</li> <li>(5) RHC composite assessment only;</li> <li>(6) ECHO composite assessment only.</li> </ol> <p>The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.</p> <p><b>Note</b></p> <p>5. Definition of response to a PAH agent or prior vasodilator treatment.</p> <p>For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>6. Authority approval requirements.</p> <p>(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.</p> <p>All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.</p>					

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	Bosentan only:					
	<p>Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.</p>					
	(b) Continuation of treatment.					
	<p>Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.</p>					
	(c) Swapping between PAH agents.					
	<p>For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.</p> <p>It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.</p> <p>To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.</p>					
	(d) Cessation of treatment — bosentan patients only.					
	<p>Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.</p> <p>For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.</p>					
	7. Re-treatment with a PAH agent.					
	<p>Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.</p>					
	8. Further information.					
	<p>A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at <a href="http://www.medicareaustralia.gov.au">www.medicareaustralia.gov.au</a>.</p>					
10130E	epoprostenol 500 microgram injection, 1 x 500 microgram vial	1	..	..	33.28 <sup>a</sup>	Veletri AT
10117L	epoprostenol 1.5 mg injection, 1 x 1.5 mg vial	1	..	..	66.55 <sup>a</sup>	Veletri AT

### OMALIZUMAB

#### Authority required

Initial treatment of uncontrolled severe allergic asthma

Initial PBS-subsidised treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with uncontrolled severe allergic asthma who has been under the care of this physician for at least 12 months, and satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:

(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or

(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or

(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

(c) FEV1 less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months; and

(d) past or current evidence of atopy, documented by skin prick testing or RAST; and

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- (e) total serum human immunoglobulin E (IgE) greater than or equal to 76 IU/mL; and
- (f) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (g) has failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented (see NOTE). Optimised asthma therapy includes:
- (i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or formoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND
- (ii) oral corticosteroids (at least 10 mg per day prednisolone (or equivalent)) for at least 6 weeks, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [[www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)].

The initial IgE assessment must be no more than 12 months old at the time of application. A re-assessment of free IgE can only be made at least 12 months after the last dose of omalizumab. For patients re-commencing omalizumab within 12 months of the last dose the previous pre-omalizumab IgE level should be used.

The IgE pathology report must be provided with the authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
- (b) while on oral corticosteroids and in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))) which includes the following:
- (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
- (ii) details of severe exacerbation/s experienced while on oral corticosteroids (date and treatment); and
- (iii) the signed patient acknowledgement; and
- (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com))

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

Where fewer than the required number of repeats to complete 28 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 28 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 24 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 24 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

### **Authority required**

#### **Continuing treatment**

Continuing PBS-subsidised treatment with omalizumab, by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient who:

- (a) has a documented history of severe allergic asthma; and
- (b) has demonstrated or sustained an adequate response to treatment with omalizumab.

An adequate response to omalizumab treatment is defined as:

- (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR
- (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))) which includes details of maintenance oral corticosteroid dose; and
- (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com))

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. If the same physician cannot assess the patient please call Medicare Australia on 1800 700 270.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

### Authority required

Initial PBS-subsidised treatment of severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfather patients)

Initial PBS-subsidised supply for continuing treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with severe allergic asthma who satisfies the following criteria:

- (a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:
  - (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or
  - (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or
  - (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and
- (b) duration of asthma of at least 1 year; and
- (c) past or current evidence of atopy, documented by skin prick testing or RAST; and
- (d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment for grandfathered patients; and
- (e) prior to omalizumab therapy had failed to achieve adequate control with optimised asthma therapy. Optimised asthma therapy includes:
  - (i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or formoterol 12 micrograms bd) for at least 12 months, and
  - (ii) may have included maintenance dose oral corticosteroids; and
- (f) has demonstrated an adequate response to treatment with omalizumab.

A review of the patient's records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include:

- (i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5;
- (ii) an improvement of at least 0.5 in the Asthma Quality of Life Questionnaire (AQLQ or mini-AQLQ);
- (iii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or
- (iv) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months

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prior to commencement of omalizumab.

Where baseline assessments are not available, please call Medicare Australia on 1800 700 270 to discuss.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted contraindications and toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following:
  - (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
  - (ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and
  - (iii) the signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 24 weeks.

An assessment of the patient's continued response to this course of PBS-subsidised treatment must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

### **Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe omalizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

### **Note**

#### TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment.

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

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	<p>Initial treatment authorisations will be limited to provide for a maximum of 28 weeks of therapy with omalizumab.</p> <p>A patient must be assessed for response to a course of Initial PBS-subsidised treatment following a minimum of 24 weeks of therapy with omalizumab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date of assessment.</p> <p>Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.</p> <p>For second and subsequent courses of PBS-subsidised omalizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.</p> <p>(b) Continuing treatment.</p> <p>Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.</p> <p>It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted omalizumab supply.</p> <p>Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply.</p> <p>Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.</p> <p>(2) Baseline measurements to determine response.</p> <p>Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.</p> <p>(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy.</p> <p>A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.</p> <p>(4) Patients 'grandfathered' onto PBS-subsidised treatment with omalizumab.</p> <p>A patient who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 November 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial 'grandfather' treatment restriction.</p> <p>A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this criterion.</p> <p>Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.</p> <p>'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). For the second and subsequent cycles, a 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' above for further details.</p> <p>(5) Monitoring of patients.</p> <p>Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>						
	<b>Note</b>						
	Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at <a href="http://www.medicareaustralia.gov.au">www.medicareaustralia.gov.au</a> or <a href="http://www.nationalasthma.org.au">www.nationalasthma.org.au</a> ); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).						
	<b>Note</b>						
	Special Pricing Arrangements apply.						
10118M	omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	..	..	250.00	Xolair	NV
10109C	omalizumab 150 mg/mL injection, 1 x 1 mL syringe	1	..	..	357.00	Xolair	NV

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### **EPOPROSTENOL**

#### **Authority required**

Initial (new patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:

- (a) WHO Functional Class IV primary pulmonary hypertension; OR
- (b) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [[www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)] which includes results from the 3 tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and
  - (iii) 6MWT; and
- (3) a signed patient acknowledgment form.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

#### **Authority required**

Initial (change or re-commencement for all patients)

Application for initial PBS-subsidised treatment with epoprostenol sodium of patients with one of the following:

- (a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised epoprostenol sodium after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with epoprostenol sodium; OR
- (b) WHO Functional Class IV primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have received prior treatment with a PBS-subsidised PAH agent other than epoprostenol sodium; OR
- (c) WHO Functional Class III primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and who have failed to respond to a prior PBS-subsidised PAH agent.

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [[www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
- (3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
- (4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent; and
- (5) for WHO Functional Class III patients, where this is the first application for epoprostenol sodium, assessment details of the PBS-subsidised PAH agent they have failed to respond to.

Where fewer than 3 tests (see requirement 2 above) are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application [see Note for test requirements].

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

#### **Authority required**

Continuing treatment (all patients)

Continuing PBS-subsidised treatment with epoprostenol sodium of patients who have received approval for initial PBS-subsidised treatment with epoprostenol sodium, and who have been assessed by a physician from a designated hospital to have achieved a response to their most recent course of epoprostenol sodium treatment [see Note for definition of response].

Applications for authorisation must be in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [[www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)] which includes results from the 3 tests below, where available:
  - (i) RHC composite assessment; and
  - (ii) ECHO composite assessment; and

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(iii) 6MWT.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

### **Note**

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

Written applications for authority to prescribe PAH agents should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

### **Note**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of agents for primary pulmonary hypertension and pulmonary arterial hypertension. Where the term PAH agents appears in the following notes and restrictions it refers to bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate, ambrisentan and tadalafil.

Patients are eligible for PBS-subsidised treatment with only 1 of the above PAH agents at any 1 time. Eligible patients may only swap between PAH agents if they have not failed prior PBS-subsidised treatment with that agent.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of that predicted.

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients with:

(a) bosentan monohydrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology), in patients with disease of WHO Functional Class III or IV severity; AND

(b) iloprost trometamol, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

— drug-induced pulmonary arterial hypertension, in patients with disease of WHO Functional Class III and IV severity; AND

(c) epoprostenol sodium, of:

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity and who have failed to respond to prior PBS-subsidised treatment with an alternate PAH agent; AND

— primary pulmonary hypertension, or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity; AND

(e) ambrisentan, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III or IV severity; AND

(f) tadalafil, of primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease, in patients with disease of WHO Functional Class III severity.

From 1 April 2012, patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

1. Definition of primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology).

Primary pulmonary hypertension, drug-induced pulmonary arterial hypertension, pulmonary arterial hypertension secondary to connective tissue disease, including scleroderma, or pulmonary arterial hypertension associated with a congenital systemic-to-pulmonary shunt (including Eisenmenger's physiology) are defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than 25 mmHg at rest and pulmonary capillary wedge pressure (PCWP) less than 18 mmHg; or

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	<p>(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or</p> <p>(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.</p> <p>2. Definition of WHO Functional Class III or IV disease severity.</p> <p>(a) WHO Functional Class III disease severity is defined as follows:</p> <p>Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.</p> <p>(b) WHO Functional Class IV disease severity is defined as follows:</p> <p>Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.</p> <p>3. Designated hospitals.</p> <p>Refer to the Medicare Australia website at <a href="http://www.medicareaustralia.gov.au">www.medicareaustralia.gov.au</a> for a list of designated hospitals.</p> <p>4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.</p> <p>(a) Initiation of treatment.</p> <p>The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph (ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.</p> <p>Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:</p> <ol style="list-style-type: none"> <li>(1) RHC plus ECHO composite assessments;</li> <li>(2) RHC composite assessment plus 6MWT;</li> <li>(3) RHC composite assessment only.</li> </ol> <p>In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:</p> <ol style="list-style-type: none"> <li>(1) ECHO composite assessment plus 6MWT;</li> <li>(2) ECHO composite assessment only.</li> </ol> <p>Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.</p> <p>(b) Continuation of treatment.</p> <p>The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:</p> <ol style="list-style-type: none"> <li>(1) RHC plus ECHO composite assessments plus 6MWT;</li> <li>(2) RHC plus ECHO composite assessments;</li> <li>(3) RHC composite assessment plus 6MWT;</li> <li>(4) ECHO composite assessment plus 6MWT;</li> <li>(5) RHC composite assessment only;</li> <li>(6) ECHO composite assessment only.</li> </ol> <p>The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application. The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.</p> <p><b>Note</b></p> <p>5. Definition of response to a PAH agent or prior vasodilator treatment.</p> <p>For patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.</p> <p>6. Authority approval requirements.</p> <p>(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.</p> <p>All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.</p>					

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	Bosentan only:					
	<p>Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.</p>					
	(b) Continuation of treatment.					
	<p>Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.</p> <p>The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated. Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.</p>					
	(c) Swapping between PAH agents.					
	<p>For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.</p> <p>It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.</p> <p>To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.</p>					
	(d) Cessation of treatment — bosentan patients only.					
	<p>Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.</p> <p>For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.</p>					
	7. Re-treatment with a PAH agent.					
	<p>Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.</p>					
	8. Further information.					
	<p>A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at <a href="http://www.medicareaustralia.gov.au">www.medicareaustralia.gov.au</a>.</p>					
10111E	epoprostenol 500 microgram injection, 1 x 500 microgram vial	1	..	..	43.37 <sup>a</sup>	Veletri AT
10129D	epoprostenol 1.5 mg injection, 1 x 1.5 mg vial	1	..	..	77.31 <sup>a</sup>	Veletri AT

### OMALIZUMAB

#### Authority required

Initial treatment of uncontrolled severe allergic asthma

Initial PBS-subsidised treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with uncontrolled severe allergic asthma who has been under the care of this physician for at least 12 months, and satisfies the following criteria:

(a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:

(i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or

(ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or

(iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and

(b) duration of asthma of at least 1 year; and

(c) FEV1 less than or equal to 80% predicted, documented on 3 or more occasions in the previous 12 months; and

(d) past or current evidence of atopy, documented by skin prick testing or RAST; and

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					Qty \$		

- (e) total serum human immunoglobulin E (IgE) greater than or equal to 76 IU/mL; and
- (f) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (g) has failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented (see NOTE). Optimised asthma therapy includes:
- (i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or formoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated, AND
- (ii) oral corticosteroids (at least 10 mg per day prednisolone (or equivalent)) for at least 6 weeks, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [[www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)].

The initial IgE assessment must be no more than 12 months old at the time of application. A re-assessment of free IgE can only be made at least 12 months after the last dose of omalizumab. For patients re-commencing omalizumab within 12 months of the last dose the previous pre-omalizumab IgE level should be used.

The IgE pathology report must be provided with the authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
- (b) while on oral corticosteroids and in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))) which includes the following:
- (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
- (ii) details of severe exacerbation/s experienced while on oral corticosteroids (date and treatment); and
- (iii) the signed patient acknowledgement; and
- (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com))

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

Where fewer than the required number of repeats to complete 28 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 28 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 28 weeks.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, must be made at around 24 to 26 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab. It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 24 to 26 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

### **Authority required**

#### Continuing treatment

Continuing PBS-subsidised treatment with omalizumab, by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient who:

- (a) has a documented history of severe allergic asthma; and
- (b) has demonstrated or sustained an adequate response to treatment with omalizumab.

An adequate response to omalizumab treatment is defined as:

- (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR
- (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline.

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					Qty	\$	

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))) which includes details of maintenance oral corticosteroid dose; and
- (c) a completed Asthma Control Questionnaire (ACQ-5) calculation sheet including the date of assessment of the patient's symptoms. (For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com))

All applications for continuing treatment with omalizumab must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, and the assessment of oral corticosteroid dose, must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab. If the same physician cannot assess the patient please call Medicare Australia on 1800 700 270.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

### **Authority required**

Initial PBS-subsidised treatment of severe allergic asthma in a patient who has previously received non-PBS-subsidised therapy with omalizumab (grandfather patients)

Initial PBS-subsidised supply for continuing treatment with omalizumab by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, of a patient aged 12 years or older with severe allergic asthma who satisfies the following criteria:

- (a) has a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features, including:
  - (i) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or
  - (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or
  - (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; and
- (b) duration of asthma of at least 1 year; and
- (c) past or current evidence of atopy, documented by skin prick testing or RAST; and
- (d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment for grandfathered patients; and
- (e) prior to omalizumab therapy had failed to achieve adequate control with optimised asthma therapy. Optimised asthma therapy includes:
  - (i) adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or formoterol 12 micrograms bd) for at least 12 months, and
  - (ii) may have included maintenance dose oral corticosteroids; and
- (f) has demonstrated an adequate response to treatment with omalizumab.

A review of the patient's records should be conducted to extract pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations. Examples of parameters to establish response include:

- (i) a reduction in Asthma Control Questionnaire (ACQ-5) score of at least 0.5;
- (ii) an improvement of at least 0.5 in the Asthma Quality of Life Questionnaire (AQLQ or mini-AQLQ);
- (iii) maintenance oral corticosteroid dose reduced by at least 25% from baseline; and/or
- (iv) a reduction in the number of hospitalisations or severe exacerbations requiring use of systemic corticosteroids, compared to the 12 months

## 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.		Brand Name and Manufacturer
					Qty \$		

prior to commencement of omalizumab.

Where baseline assessments are not available, please call Medicare Australia on 1800 700 270 to discuss.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application. Details of the accepted contraindications and toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

- (a) a completed authority prescription form; and
- (b) a completed Severe Allergic Asthma PBS Authority Application - Supporting Information Form (may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)) which includes the following:
  - (i) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
  - (ii) details of pre- and post-omalizumab data on symptoms, quality of life, medication doses, exacerbations and hospitalisations; and
  - (iii) the signed patient acknowledgement.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

Where fewer than the required number of repeats to complete 24 weeks of treatment are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks of omalizumab therapy may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period beyond 24 weeks.

An assessment of the patient's continued response to this course of PBS-subsidised treatment must be made at around 20 to 22 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. The same parameters used to establish response to non-PBS-subsidised therapy with omalizumab should be used for the assessment.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted to Medicare Australia within this timeframe, the patient will be deemed to have failed to respond to treatment with omalizumab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 20 to 22 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised omalizumab treatment.

Patients are eligible to receive continuing courses of omalizumab treatment of up to 24 weeks providing they continue to demonstrate an adequate response to treatment.

Patients may qualify for PBS-subsidised treatment under this restriction once only. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased

### **Note**

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

Prescribing information (including Authority Application Forms) is available on the Medicare Australia website at www.medicareaustralia.gov.au.

Written applications for authority to prescribe omalizumab should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

### **Note**

#### TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

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

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment.

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

## 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	
	<p>Initial treatment authorisations will be limited to provide for a maximum of 28 weeks of therapy with omalizumab.</p> <p>A patient must be assessed for response to a course of Initial PBS-subsidised treatment following a minimum of 24 weeks of therapy with omalizumab, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date of assessment.</p> <p>Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.</p> <p>For second and subsequent courses of PBS-subsidised omalizumab treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.</p> <p>(b) Continuing treatment.</p> <p>Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.</p> <p>It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted omalizumab supply.</p> <p>Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply.</p> <p>Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with omalizumab.</p> <p>(2) Baseline measurements to determine response.</p> <p>Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) and oral corticosteroid dose, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Medicare Australia will assess response according to these revised baseline measurements.</p> <p>(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy.</p> <p>A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (oral corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.</p> <p>(4) Patients 'grandfathered' onto PBS-subsidised treatment with omalizumab.</p> <p>A patient who commenced treatment with omalizumab for uncontrolled severe allergic asthma prior to 1 November 2010 and who continues to receive treatment at the time of application, may qualify for treatment under the Initial 'grandfather' treatment restriction.</p> <p>A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with omalizumab will be authorised under this criterion.</p> <p>Following completion of the Initial PBS-subsidised course, further applications for treatment with omalizumab will be assessed under the continuing treatment restriction.</p> <p>'Grandfather' arrangements will only apply for the first treatment cycle (initial treatment course with or without continuing treatment course/s). For the second and subsequent cycles, a 'Grandfathered' patient must re-qualify for Initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 6 month break in PBS-subsidised therapy' above for further details.</p> <p>(5) Monitoring of patients.</p> <p>Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>						
	<p><b>Note</b></p> <p>Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at <a href="http://www.medicareaustralia.gov.au">www.medicareaustralia.gov.au</a> or <a href="http://www.nationalasthma.org.au">www.nationalasthma.org.au</a>); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).</p>						
	<p><b>Note</b></p> <p>Special Pricing Arrangements apply.</p>						
10110D	omalizumab 75 mg/0.5 mL injection, 1 x 0.5 mL syringe	1	..	..	266.76	Xolair	NV
10122R	omalizumab 150 mg/mL injection, 1 x 1 mL syringe	1	..	..	378.04	Xolair	NV

## SECTION 100 (IVF/GIFT TREATMENT)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	Price ex manufacturer \$	Brand Name and Manufacturer	
<p><b>CORIFOLLITROPIN ALFA</b>  <u>Criteria for availability</u>            Controlled ovarian stimulation</p> <p><b>Clinical criteria:</b>            Patient must have an antral follicle count of 20 or less.</p> <p><b>Treatment criteria:</b>            Patient must be undergoing treatment as described in items 13200, 13201 or 13202 of the Health Insurance (General Medical Services Table) Regulations,</p> <p><b>AND</b>            Patient must be undergoing a gonadotrophin releasing hormone antagonist cycle.</p> <p><b>Note</b>            Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact the Department of Human Services on 1800 700 270.</p>					
5816D	corifollitropin alfa 100 microgram/0.5 mL injection, 1 x 0.5 mL syringe	1	410.14	Elonva	MK
<p><b>PROGESTERONE</b>  <u>Criteria for availability</u>            Luteal support as part of an assisted reproductive technology (ART) treatment programme for infertile women</p> <p><b>Clinical criteria:</b>            The treatment must be for luteal phase support,</p> <p><b>AND</b>            Patient must be receiving medical treatment as described in items 13200 or 13201 of the Health Insurance (General Medical Services Table) Regulations.            The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.</p> <p><b>Note</b>            Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact the Department of Human Services on 1800 700 270.</p>					
10116K	progesterone 100 mg pessary, 21	1	49.39	Endometrin	FP
9608Q	progesterone 100 mg pessary, 15	1	50.40	Oripro	ON
9609R	progesterone 200 mg pessary, 15	1	55.60	Oripro	ON
<p><b>PROGESTERONE</b>  <u>Criteria for availability</u>            Luteal support as part of an assisted reproductive technology (ART) treatment programme for infertile women</p> <p><b>Clinical criteria:</b>            The treatment must be for luteal phase support,</p> <p><b>AND</b>            Patient must be receiving medical treatment as described in items 13200 or 13201 of the Health Insurance (General Medical Services Table) Regulations.            The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.</p> <p><b>Note</b>            Supply of these items is through an accredited IVF/GIFT clinic. For enquiries relating to the IVF/GIFT Program, medical practitioners should contact the Department of Human Services on 1800 700 270.</p> <p><b>Note</b>            Special Pricing Arrangements apply.</p>					
6366C	progesterone 8% vaginal gel, 15 applications	1	148.50	Crinone 8%	SG