Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS FOR APPROVED PHARMACISTS AND MEDICAL PRACTITIONERS

SUMMARY OF CHANGES

EFFECTIVE 1 AUGUST 2007

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 August 2007. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 August 2007 and are included, where applicable, in prices published in the Schedule—

Dispensing Fees:	Ready-prepared	$5.44
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$7.48
Additional Fees (for safety net prices):	Ready-prepared	$1.01
	Extemporaneously-prepared	$1.40
Patient Co-payments:	General	$30.70
	Concessional	$4.90
Safety Net Thresholds:	General	$1059.00
	Concessional	$274.40
Safety Net Card Issue Fee:		$7.72

SUMMARY OF CHANGES

ADDITIONS

Additions - Items

(see under 'RESTRICTIONS' and 'NOTES' below for items where a restriction and/or a note applies)

2246F **Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids**, Compound powder 400 g (*Neocate LCP*)

2560R **Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids**, Compound powder 400 g (*Neocate LCP*) **(Diff. Restriction)**

2244D **Amino acids—synthetic, formula**, Compound powder 400 g (*Neocate Advance Tropical Flavour*)

2553J **Amino acids—synthetic, formula**, Compound powder 400 g (*Neocate Advance Tropical Flavour*) **(Diff. Restriction)**

1343Q **Amlodipine**, Tablet 5 mg (as maleate) (*Amlo 5*)

1345T **Amlodipine**, Tablet 10 mg (as maleate) (*Amlo 10*)

2978R **Cholestyramine**, Sachets 9.4 g (equivalent to 8 g cholestyramine), 50 (*Questran Lite*)

2478K **Dasatinib**, Tablet 20 mg (*Sprycel*)

2482P **Dasatinib**, Tablet 50 mg (*Sprycel*)

2485T **Dasatinib**, Tablet 70 mg (*Sprycel*)

2214M **Mesalazine**, Tablet 500 mg (prolonged release) (*Pentasa*)

2234N **Mesalazine**, Sachet containing prolonged release granules, 1 g per sachet (*Pentasa*)

2287J **Mesalazine**, Sachet containing prolonged release granules, 2 g per sachet (*Pentasa*)

2172H **Methylphenidate hydrochloride**, Tablet 27 mg (extended release) (*Concerta*)

2190G **Perindopril with indapamide hemihydrate**, Tablet containing 2.5 mg perindopril arginine-0.625 mg indapamide hemihydrate (*Coversyl Plus LD 2.5mg/0.625mg*)

2626F **Ramipril with felodipine**, Tablet 2.5 mg-2.5 mg (modified release) (*Triasyn 2.5/2.5*)

2629J **Ramipril with felodipine**, Tablet 5 mg-5 mg (modified release) (*Triasyn 5.0/5.0*)

1371E **Ranibizumab**, Solution for intravitreal injection 3 mg in 0.3 mL (*Lucentis*)

1382R **Ranibizumab**, Solution for intravitreal injection 3 mg in 0.3 mL (*Lucentis*) **(Diff. Max. Rpts)**

2700D **Thyrotropin alfa**, Powder for injection 0.9 mg, 2 (*Thyrogen*)

1349B **Verteporfin**, Powder for I.V. infusion 15 mg (*Visudyne*)

Additions - Brands

8594H *Amisulpride 100 Winthrop, WA* — **Amisulpride**, Tablet 100 mg

8595J *Amisulpride 200 Winthrop, WA* — **Amisulpride**, Tablet 200 mg

8596K *Amisulpride 400 Winthrop, WA* — **Amisulpride**, Tablet 400 mg

2751T *Amlodipine Sandoz, SZ; Perivasc, AF* — **Amlodipine**, Tablet 5 mg (as besylate)

2752W *Amlodipine Sandoz, SZ; Perivasc, AF* — **Amlodipine**, Tablet 10 mg (as besylate)

8254K *Clavycillin 875/125, CR* — **Amoxycillin with clavulanic acid**, Tablet 875 mg-125 mg

5006L *Clavycillin 875/125, CR* — **Amoxycillin with clavulanic acid**, Tablet 875 mg-125 mg **(Dental)**

1209P *Ciprofloxacin 500, CR* — **Ciprofloxacin**, Tablet 500 mg

1210Q *Ciprofloxacin 750, CR* — **Ciprofloxacin**, Tablet 750 mg

8220P *Citalopram 20, CR* — **Citalopram hydrobromide**, Tablet 20 mg (base)

1312C *Diltahexal CD, WA* — **Diltiazem hydrochloride**, Capsule 180 mg (controlled delivery)

1313D *Diltahexal CD, WA* — **Diltiazem hydrochloride**, Capsule 240 mg (controlled delivery)

8480H *Diltahexal CD, WA* — **Diltiazem hydrochloride**, Capsule 360 mg (controlled delivery)

8828P *Adriamycin, PF* — **Doxorubicin hydrochloride**, Solution for I.V. injection or intravesical administration 200 mg in 100 mL

1434L *Fluoxetine 20, CR* — **Fluoxetine hydrochloride**, Capsule 20 mg (base)

8400D *Fosinopril/HCT Sandoz 10 mg/12.5 mg, SZ* — **Fosinopril sodium with hydrochlorothiazide**, Tablet 10 mg-12.5 mg
8401E *Fosinopril/HCT Sandoz 20 mg/12.5 mg, SZ* — **Fosinopril sodium with hydrochlorothiazide**, Tablet 20 mg-12.5 mg
8559L *Gabaran, RA* — **Gabapentin**, Tablet 600 mg
8389M *Gabaran, RA* — **Gabapentin**, Tablet 800 mg
9039R *Lantus SoloStar, AV* — **Insulin glargine**, Injections (human analogue) 100 units per mL, 3 mL, 5
2456G *Lisinopril Winthrop, SZ* — **Lisinopril**, Tablet 5 mg
2457H *Lisinopril Winthrop, SZ* — **Lisinopril**, Tablet 10 mg
2458J *Lisinopril Winthrop, SZ* — **Lisinopril**, Tablet 20 mg
8561N *Chem mart Meloxicam 7.5 mg, CH; GenRx Meloxicam, GX; Moxicam 7.5, AF; Terry White Chemists Meloxicam 7.5 mg, TW* — **Meloxicam**, Tablet 7.5 mg
8562P *Chem mart Meloxicam 15 mg, CH; GenRx Meloxicam, GX; Moxicam 15, AF; Terry White Chemists Meloxicam 15 mg, TW* — **Meloxicam**, Tablet 15 mg
1932Q *Mitozantrone Ebewe, IT* — **Mitozantrone hydrochloride**, Injection 10 mg (base) in 5 mL
1929M *Mitozantrone Ebewe, IT* — **Mitozantrone hydrochloride**, Injection 20 mg (base) in 10 mL
8226Y *PF* — **Ondansetron**, I.V. injection 4 mg in 2 mL
1596B *PF* — **Ondansetron**, I.V. injection 4 mg in 2 mL **(Diff. Restriction)**
8227B *PF* — **Ondansetron**, I.V. injection 8 mg in 4 mL
1597C *PF* — **Ondansetron**, I.V. injection 8 mg in 4 mL **(Diff. Restriction)**
8039D *Oxybutynin Sandoz, SZ* — **Oxybutynin hydrochloride**, Tablet 5 mg
3050M *Perindopril-DP, GM* — **Perindopril**, Tablet containing 2 mg perindopril erbumine
3051N *Perindopril-DP, GM* — **Perindopril**, Tablet containing 4 mg perindopril erbumine
8704D *Perindopril-DP, GM* — **Perindopril**, Tablet containing 8 mg perindopril erbumine
8449Q *Chem mart Perindopril/Indapamide 4/1.25, CH; GenRx Perindopril/Indapamide 4/1.25, GX; Terry White Chemists Perindopril/Indapamide 4/1.25, TW* — **Perindopril with indapamide hemihydrate**, Tablet containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate
2289L *Valproate Winthrop EC 200, WA* — **Sodium valproate**, Tablet 200 mg (enteric coated)
2290M *Valproate Winthrop EC 500, WA* — **Sodium valproate**, Tablet 500 mg (enteric coated)
2791X *Tranalpha, AF* — **Trandolapril**, Capsule 500 micrograms
2792Y *Tranalpha, AF* — **Trandolapril**, Capsule 1 mg
2793B *Tranalpha, AF* — **Trandolapril**, Capsule 2 mg
8758Y *Tranalpha, AF* — **Trandolapril**, Capsule 4 mg

BIOEQUIVALENCE INDICATORS

The bioequivalence indicator ([a]) has been added to the following **brands**:

8594H *Solian 100, SW* — **Amisulpride**, Tablet 100 mg
8595J *Solian 200, SW* — **Amisulpride**, Tablet 200 mg
8596K *Solian 400, SW* — **Amisulpride**, Tablet 400 mg
2752W *Norvasc, PF* — **Amlodipine**, Tablet 10 mg (as besylate)
2751T *Norvasc, PF* — **Amlodipine**, Tablet 5 mg (as besylate)
8828P *Doxorubicin Ebewe, IT* — **Doxorubicin hydrochloride**, Solution for I.V. injection or intravesical administration 200 mg in 100 mL
8400D *Monoplus 10/12.5, BQ* — **Fosinopril sodium with hydrochlorothiazide**, Tablet 10 mg-12.5 mg
8401E *Monoplus 20/12.5, BQ* — **Fosinopril sodium with hydrochlorothiazide**, Tablet 20 mg-12.5 mg
8559L *Neurontin, PF* — **Gabapentin**, Tablet 600 mg
1932Q *PU* — **Mitozantrone hydrochloride**, Injection 10 mg (base) in 5 mL
8039D *Ditropan, SW* — **Oxybutynin hydrochloride**, Tablet 5 mg

The bioequivalence indicator ([a]) has been deleted from the following **brands**:

2576N *Mylanta P, PC* — **Aluminium hydroxide with magnesium hydroxide**, Tablet 200 mg-200 mg

2157M *Mylanta P, PC* — **Aluminium hydroxide with magnesium hydroxide**, Oral suspension 200 mg-200 mg per 5 mL, 500 mL

DELETIONS

Deletions - Item

1508J **Hydroxocobalamin**, Injection 1 mg in 1 mL (*Neo-Cytamen*)

Deletions - PBS Therapeutic Group Premium Exemption Items

8923P **Amlodipine besylate**, Tablet 5 mg (base) (*Norvasc*)

8924Q **Amlodipine besylate**, Tablet 10 mg (base) (*Norvasc*)

Deletions - Brands

2576N *Gelusil, WW* — **Aluminium hydroxide with magnesium hydroxide**, Tablet 200 mg-200 mg

2157M *Gelusil, WW* — **Aluminium hydroxide with magnesium hydroxide**, Oral suspension 200 mg-200 mg per 5 mL, 500 mL

2502Q *Sitriol, AL* — **Calcitriol**, Capsule 0.25 microgram

1526H *Floxsig, SI* — **Flucloxacillin**, Capsule 250 mg

5090X *Floxsig, SI* — **Flucloxacillin**, Capsule 250 mg **(Dental)**

1527J *Floxsig, SI* — **Flucloxacillin**, Capsule 500 mg

5091Y *Floxsig, SI* — **Flucloxacillin**, Capsule 500 mg **(Dental)**

8449Q *Coversyl Plus 4/1.25, SE* — **Perindopril with Indapamide Hemihydrate**, Tablet containing 4 mg perindopril erbumine-1.25 mg indapamide hemihydrate

ALTERATIONS

Alterations - Items

From:
2751T **Amlodipine besylate**, Tablet 5 mg (base)
To:
2751T **Amlodipine**, Tablet 5 mg (as besylate)

From:
2752W **Amlodipine besylate**, Tablet 10 mg (base)
To:
2752W **Amlodipine**, Tablet 10 mg (as besylate)

Alterations - Restrictions

(see under 'RESTRICTIONS' below for full details)

8737W **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*) [for the treatment of severe active rheumatoid arthritis]

8741C **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*) **(Diff. Max. Rpts)** [for the treatment of severe active rheumatoid arthritis]

8773R **Anakinra**, Injection 100 mg in 0.67 mL single use pre-filled syringe (*Kineret*) [for the treatment of severe active rheumatoid arthritis]

8774T **Anakinra**, Injection 100 mg in 0.67 mL single use pre-filled syringe (*Kineret*) **(Diff. Max. Rpts)** [for the treatment of severe active rheumatoid arthritis]

8796Y **Budesonide with eformoterol fumarate dihydrate**, Powder for oral inhalation in breath actuated device 100 micrograms-6 micrograms per dose (120 doses) (*Symbicort Turbuhaler 100/6*)

8625Y **Budesonide with eformoterol fumarate dihydrate**, Powder for oral inhalation in breath actuated device 200 micrograms-6 micrograms per dose (120 doses) (*Symbicort Turbuhaler 200/6*)

8637N **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) [for the treatment of severe active rheumatoid arthritis]

8638P **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)** [for the treatment of severe active rheumatoid arthritis]

8861J **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) [for the treatment of severe active rheumatoid arthritis]

8862K **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)** [for the treatment of severe active rheumatoid arthritis]

9089J **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) [for the treatment of severe active rheumatoid arthritis]

9090K **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) **(Diff. Max. Rpts)** [for the treatment of severe active rheumatoid arthritis]

8757X **Ezetimibe**, Tablet 10 mg (*Ezetrol*)

8881K **Ezetimibe with simvastatin**, Tablet 10 mg-40 mg (*Vytorin*)

8882L **Ezetimibe with simvastatin**, Tablet 10 mg-80 mg (*Vytorin*)

8519J **Fluticasone propionate with salmeterol xinafoate**, Oral pressurised inhalation 250 micrograms-25 micrograms (base) per dose (120 doses), CFC-free formulation (*Seretide MDI 250/25*)

8432T **Fluticasone propionate with salmeterol xinafoate**, Powder for oral inhalation in breath actuated device 500 micrograms-50 micrograms (base) per dose (60 doses) (*Seretide Accuhaler 500/50*)

8373Q **Leflunomide**, Pack containing 3 tablets leflunomide 100 mg and 30 tablets leflunomide 20 mg (*Arava*)

8374R **Leflunomide**, Tablet 10 mg (*Arabloc, Arava*)

8375T **Leflunomide**, Tablet 20 mg (*Arabloc, Arava*)

8245Y **Letrozole**, Tablet 2.5 mg (*Femara 2.5 mg*)

8633J **Levonorgestrel**, Intrauterine drug delivery system 52 mg (releasing approximately 20 micrograms per 24 hours) (*Mirena*)

8612G **Macrogol 3350**, Sachets containing powder for solution 13.125g with electrolytes, 30 (*Movicol)*

8481J **Risedronate sodium**, Tablet 5 mg (*Actonel*)

8621R **Risedronate sodium**, Tablet 35 mg (*Actonel Once-a-Week*)

8899J **Risedronate sodium and calcium carbonate**, Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium) (*Actonel Combi*)

9057Q **Travoprost with timolol maleate**, Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL (*Duotrav*)

NOTES

Additions - Notes

(see under 'NOTES' below for full details)

Notes have been **added** in respect of the following:

Amlodipine

8750M **Budesonide with eformoterol fumarate dihydrate**, Powder for oral inhalation in breath actuated devices 400 micrograms-12 micrograms per dose (60 doses), 2 (*Symbicort Turbuhaler 400/12*)

8519J **Fluticasone propionate with salmeterol xinafoate**, Oral pressurised inhalation 250 micrograms-25 micrograms (base) per dose (120 doses), CFC-free formulation (*Seretide MDI 250/25*)

8432T **Fluticasone propionate with salmeterol xinafoate**, Powder for oral inhalation in breath actuated device 500 micrograms-50 micrograms (base) per dose (60 doses) (*Seretide Accuhaler 500/50*)

Alterations - Notes

(see under 'NOTES' below for full details)

Notes have been **amended** in respect of the following:

Adalimumab [for the treatment of severe active rheumatoid arthritis]

Anakinra [for the treatment of severe active rheumatoid arthritis]

Dihydropyridine derivatives

Diphtheria and tetanus vaccine, adsorbed, diluted for adult use

Etanercept [for the treatment of severe active rheumatoid arthritis]

Letrozole

Perindopril with indapamide hemihydrate

		From	*To*
8637N	**Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)	WY	WX
8638P	**Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
8778B	**Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
8779C	**Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9035M	**Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9036N	**Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9037P	**Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
8861J	**Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)	WY	WX
8862K	**Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9038Q	**Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9081Y	**Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9082B	**Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9083C	**Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9084D	**Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9085E	**Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)	WY	WX
9086F	**Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9087G	**Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9088H	**Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9089J	**Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9090K	**Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
9091L	**Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*) **(Diff. Max. Rpts)**	WY	WX
8825L	**Glucose indicator—blood**, Electrode strips, 50 (*TrueTrack*)	DR	DB
1502C	**Hydrocortisone acetate**, Rectal foam 90 mg per applicatorful, 14 applications, aerosol 21.1 g (*Colifoam*)	GC	AS
8198L	**Lansoprazole**, Capsule 15 mg (*Zoton*)	WY	WX
2240X	**Lansoprazole**, Capsule 30 mg (*Zoton*)	WY	WX
2241Y	**Lansoprazole**, Capsule 30 mg (*Zoton*) **(Diff. Max. Rpts)**	WY	WX
8528W	**Lansoprazole**, Sachet containing granules for oral suspension, 30 mg per sachet (*Zoton*) **(Special Pharmaceutical Benefit)**	WY	WX
8529X	**Lansoprazole**, Sachet containing granules for oral suspension, 30 mg per sachet (*Zoton*) **(Special Pharmaceutical Benefit) (Diff. Max. Rpts)**	WY	WX

9730D	**Lansoprazole**, Sachet containing granules for oral suspension, 30 mg per sachet (*Zoton*) **(Special Pharmaceutical Benefit)**	WY	WX
9731E	**Lansoprazole**, Sachet containing granules for oral suspension, 30 mg per sachet (*Zoton*) **(Special Pharmaceutical Benefit) (Diff. Max. Rpts)**	WY	WX
2913H	**Levonorgestrel**, Tablets 30 micrograms, 28 (*Microval 28*)	WY	WX
8282X	**Milk powder—lactose free formula**, Infant formula powder 900 g (*S-26 LF*)	WY	WX
8283Y	**Milk powder—lactose free formula**, Infant formula powder 900 g (*S-26 LF*) **(Diff. Max. Rpts)**	WY	WX
1733F	**Oestrogens—conjugated**, Tablet 300 micrograms (*Premarin*)	WY	WX
1734G	**Oestrogens—conjugated**, Tablet 625 micrograms (*Premarin*)	WY	WX
8168X	**Oestrogens—conjugated with medroxyprogesterone acetate**, Tablets 625 micrograms-2.5 mg, 28 (*Premia 2.5 Continuous*)	WY	WX
8169Y	**Oestrogens—conjugated with medroxyprogesterone acetate**, Tablets 625 micrograms-5 mg, 28 (*Premia 5 Continuous*)	WY	WX
8725F	**Sirolimus**, Oral solution 1 mg per mL, 60 mL (*Rapamune*)	WY	WX
8724E	**Sirolimus**, Tablet 1 mg (*Rapamune*)	WY	WX
8833X	**Sirolimus**, Tablet 2 mg (*Rapamune*)	WY	WX
8302Y	**Venlafaxine hydrochloride**, Capsule 150 mg (base) (modified release) (*Efexor-XR*)	WY	WX
8868R	**Venlafaxine hydrochloride**, Capsule 37.5 mg (base) (modified release) (*Efexor-XR*)	WY	WX
8301X	**Venlafaxine hydrochloride**, Capsule 75 mg (base) (modified release) (*Efexor-XR*)	WY	WX

SECTION 100 - HIGHLY SPECIALISED DRUGS PROGRAM
ADDITIONS

Additions - Items

(see under 'RESTRICTIONS' and 'NOTES' below for full details)

9611W **Rituximab**, Solution for I.V. infusion 500 mg in 50 mL (*Mabthera*)

9610T **Tipranavir**, Capsule 250 mg (*Aptivus*)

ALTERATIONS

Alterations - Restriction and Note

(see under 'RESTRICTIONS' and 'NOTES' below for full details)

6397Q **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*) [for the treatment of severe active rheumatoid arthritis]

Alterations - Manufacturer's Code

		From	*To*
6367D	**Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)	WY	WX
6437T	**Sirolimus**, Oral solution 1 mg per mL, 60 mL (*Rapamune*)	WY	WX
6436R	**Sirolimus**, Tablet 1 mg (*Rapamune*)	WY	WX
6457W	**Sirolimus**, Tablet 2 mg (*Rapamune*)	WY	WX

ADVANCE NOTICES

Advance Notices - Deletion of Items

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 **September** 2007:

Items discontinued by the manufacturer -

1048E **Ampicillin**, Capsule 250 mg (*Alphacin 250*)

5013W **Ampicillin**, Capsule 250 mg (*Alphacin 250*) **(Dental)**

2671N **Ampicillin**, Capsule 500 mg (*Alphacin 500*)

5014X **Ampicillin**, Capsule 500 mg (*Alphacin 500*) **(Dental)**

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 **October** 2007:

Items discontinued by the manufacturer -

1425B **Insulin neutral—insulin isophane (n.p.h.), (mixed) (biphasic isophane)**, Injection (human) 100 units (50 units-50 units) per mL, 10 mL (*Mixtard 50/50*)

8006J **Insulin neutral—insulin isophane (n.p.h.), (mixed) (biphasic isophane)**, Injections (human) 100 units (20 units-80 units) per mL, 3 mL, 5 (*Mixtard 20/80 Penfill 3 mL*)

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 **January** 2008:

Items discontinued by the manufacturer -

8012Q **Oestradiol**, Transdermal patches 3.28 mg (releasing approximately 37.5 micrograms per 24 hours), 8 *(Menorest 37.5)*

8013R **Oestradiol**, Transdermal patches 4.33 mg (releasing approximately 50 micrograms per 24 hours), 8 *(Menorest 50)*

8014T **Oestradiol**, Transdermal patches 6.57 mg (releasing approximately 75 micrograms per 24 hours), 8 *(Menorest 75)*

8041F **Oestradiol**, Transdermal patches 8.66 mg (releasing approximately 100 micrograms per 24 hours), 8 *(Menorest 100)*

2163W **Thioridazine hydrochloride**, Tablet 10 mg (*Aldazine 10*)

2359E **Thioridazine hydrochloride**, Tablet 25 mg (*Aldazine 25*)

2164X **Thioridazine hydrochloride**, Tablet 50 mg (*Aldazine 50*)

2165Y **Thioridazine hydrochloride**, Tablet 100 mg (*Aldazine 100*)

Advance Notices - Deletion of Brands

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 **September** 2007:

Brand discontinued by the manufacturer -

2913H *Microval 28, WY* — **Levonorgestrel**, Tablets 30 micrograms, 28

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 **October** 2007:

Brand discontinued by the manufacturer -

1426C *Mixtard 30/70, NO* — **Insulin neutral—insulin isophane (n.p.h.), (mixed) (biphasic isophane)**, Injection (human) 100 units (30 units-70 units) per mL, 10 mL

RESTRICTIONS

The text of restrictions mentioned above:

8737W **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*)

Authority required

Initial 1 (new patients)

Application for initial PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and

(c) have failed to achieve an adequate response to the following treatments:

(i) methotrexate at a dose of at least 20 mg weekly; and

(ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and

(iii) a minimum of 3 months' treatment with:

— leflunomide alone; or

— leflunomide in combination with methotrexate; or

— cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

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

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

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks 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).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with adalimumab.

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Authority required

Initial 2 (change or re-commencement)

Application for an initial course of PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with adalimumab within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks 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).

Where the most recent course of PBS-subsidised adalimumab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised adalimumab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

8741C **Adalimumab**, Injection 40 mg in 0.8 mL pre-filled syringe (*Humira*)

Authority required

Continuing treatment
Continuing PBS-subsidised treatment with adalimumab, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with adalimumab; and
(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with adalimumab.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks 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).

All applications for continuing treatment with adalimumab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with adalimumab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with adalimumab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial adalimumab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

2244D **Amino acids—synthetic, formula**, Compound powder 400 g (*Neocate Advance Tropical Flavour*)
2246F **Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids**, Compound powder 400 g (*Neocate LCP*)

Authority required

Initial treatment, for up to 3 months, for combined intolerance (not infant colic) to cows' milk protein and protein hydrolysate formulae in a child aged less then 2 years. Combined intolerance is demonstrated when the child has failed to respond to a strict cows' milk protein free diet with a protein hydrolysate (with

or without medium chain triglycerides) as the principal formula. The date of birth of the patient must be included in the authority application

2553J **Amino acids—synthetic, formula**, Compound powder 400 g (*Neocate Advance Tropical Flavour*)
2560R **Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids**, Compound powder 400 g (*Neocate LCP*)

Authority required

Continuing treatment for combined intolerance (not infant colic) to cows' milk protein and protein hydrolysate formulae in a child aged less than 2 years, where the child has been assessed by a suitably qualified allergist or paediatrician. The date of birth of the patient must be included in the authority application

Authority required

Treatment for combined intolerance (not infant colic) to cows' milk protein and protein hydrolysate formulae in a child aged 2 years or over, where the child is assessed by a suitably qualified allergist or paediatrician at intervals not greater than 6 months. The date of birth of the patient must be included in the authority application

Authority required

Severe intestinal malabsorption including short bowel syndrome where protein hydrolysate formulae have failed

Authority required

Severe intestinal malabsorption including short bowel syndrome where the patient has been receiving parenteral nutrition

8773R **Anakinra**, Injection 100 mg in 0.67 mL single use pre-filled syringe (*Kineret*)

Authority required

Initial 1 (new patients)

Application for initial PBS-subsidised treatment with anakinra, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and

(c) have failed to achieve an adequate response to the following treatments:

(i) methotrexate at a dose of at least 20 mg weekly; and

(ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and

(iii) a minimum of 3 months' treatment with:

— leflunomide alone; or

— leflunomide in combination with methotrexate; or

— cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:

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

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

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and

(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks 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).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with anakinra.

Patients who fail to demonstrate a response to treatment with anakinra under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial anakinra after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Authority required

Initial 2 (change or re-commencement)

Application for an initial course of PBS-subsidised treatment with anakinra, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with anakinra within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised anakinra treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks 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).

Where the most recent course of PBS-subsidised anakinra treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised anakinra treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with anakinra under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial anakinra after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

8774T **Anakinra**, Injection 100 mg in 0.67 mL single use pre-filled syringe (*Kineret*)

Authority required

Continuing treatment
Continuing PBS-subsidised treatment with anakinra, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with anakinra; and
(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with anakinra.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks 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).

All applications for continuing treatment with anakinra must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with anakinra, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with anakinra under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial anakinra after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

8796Y **Budesonide with eformoterol fumarate dihydrate**, Powder for oral inhalation in breath actuated device 100 micrograms-6 micrograms per dose (120 doses) (*Symbicort Turbuhaler 100/6*)

8625Y **Budesonide with eformoterol fumarate dihydrate**, Powder for oral inhalation in breath actuated device 200 micrograms-6 micrograms per dose (120 doses) (*Symbicort Turbuhaler 200/6*)

Restricted benefit

Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide

Restricted benefit

Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled eformoterol fumarate dihydrate and budesonide

Restricted benefit

For single maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with oral corticosteroids

Restricted benefit

For single maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with inhaled corticosteroids

Restricted benefit

For maintenance and reliever therapy in a patient who experiences frequent asthma symptoms while receiving treatment with a combination of an inhaled corticosteroid and a long-acting beta-2 agonist

2478K **Dasatinib**, Tablet 20 mg (*Sprycel*)

2482P **Dasatinib**, Tablet 50 mg (*Sprycel*)

2485T **Dasatinib**, Tablet 70 mg (*Sprycel*)

Note:

Any queries concerning the arrangements to prescribe dasatinib 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.

Any queries concerning patients who are enrolled on the Dasatinib Compassionate Program may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Applications for authority to prescribe dasatinib should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Authority required

Initial treatment, as the sole PBS-subsidised therapy, of a patient with chronic myeloid leukaemia in any disease phase bearing the Philadelphia chromosome or expressing the transcript, BCR-ABL, who has active leukaemia (as defined by presence on current pathology assessments of either the Philadelphia chromosome on cytogenetic or FISH analysis, or the presence of the transcript BCR-ABL and morphological evidence of leukaemia) and who has failed an adequate trial of imatinib.

Failure of an adequate trial of imatinib is defined as:

(i) Lack of response to initial imatinib therapy, defined as either:

— failure to achieve a haematological response after a minimum of 3 months therapy with imatinib for patients initially treated in chronic phase; or

— failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib for patients initially treated in chronic phase as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or

— failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib; OR

(ii) Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib therapy; OR

(iii) Development of accelerated phase or blast crisis in a patient previously prescribed imatinib for any phase of chronic myeloid leukaemia.

Accelerated phase is defined by the presence of 1 or more of the following:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or

(2) Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%; or

(3) Peripheral basophils greater than or equal to 20%; or

(4) Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or

(5) Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome).

Blast crisis is defined as either:

(1) Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or

(2) Extramedullary involvement other than spleen and liver; OR

(iv) Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during first-line imatinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia; OR

(v) Detection of a mutation in BCR-ABL (L248V, G250E, Q252H/R, Y253H/F, E255K/V, H396P/R, and D276G) that infers high level imatinib resistance. (Patients with these mutations but without active leukaemia, will not be approved); OR

(vi) Grade 3 or 4 non-haematological toxicity that is imatinib related.

Applications for authorisation must be in writing and must include

(a) a completed authority prescription form; and

(b) a completed Chronic Myeloid Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and

(c) a signed patient acknowledgement; and

(d) a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of chronic myeloid leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. (The date of the relevant pathology report needs to be provided); and

(e) a copy of the current confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement or details of Grade 3 or 4 non-haematological toxicity.

Note:

Patients should be commenced on a dose of dasatinib of at least 100 mg (base) daily. Continuing therapy is dependent on patients demonstrating a major cytogenetic response to dasatinib therapy or a peripheral blood BCR-ABL level of less than 1% at 12 monthly intervals, irrespective of the daily dasatinib dose received.

Authority required

Continuing treatment, as the sole PBS-subsidised therapy, of a patient who has received initial treatment with dasatinib as a pharmaceutical benefit for chronic myeloid leukaemia, and who has demonstrated either a major cytogenetic response, or less than 1% BCR-ABL level in the blood, to dasatinib in the preceding 12 months.

Applications for authorisation must be in writing and must include

(1) a completed authority prescription form; and

(2) a completed Chronic Myeloid Leukaemia Dasatinib Authority Application Form for continuing treatment; and

(3) demonstration of continued response to treatment as evidenced by either:

(a) major cytogenetic response [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided; or

(b) a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response]. Where this has been supplied within the previous 12 months, only the date of the relevant pathology report need be provided

Dasatinib will only be subsidised for patients with chronic myeloid leukaemia who are not receiving concomitant PBS-subsidised imatinib mesylate or interferon alfa therapy.

Note:

Definitions of response.

A major cytogenetic response is defined as less than 35% Philadelphia positive bone marrow cells.

A bone marrow or peripheral blood BCR-ABL level of less than 1% on the international scale (Blood 108: 28-37, 2006) also indicates a response, at least the biological equivalent of a major cytogenetic response.

Authority approval requirements.

For the purposes of assessing response to PBS-subsidised treatment with dasatinib, either cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted. For bone marrow analyses, where the standard karyotyping is not informative for technical reasons, a cytogenetic analysis performed on the bone marrow by the use of fluorescence in situ hybridisation (FISH) with BCR-ABL specific probe must be submitted. The cytogenetic or peripheral blood quantitative PCR analyses must be submitted as follows:

(i) between 10 and 12 months of the commencement of treatment with dasatinib, at which time patients in whom a major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been demonstrated may receive authorisation for a further 12 months of treatment; and

(ii) at no greater than 12 month intervals thereafter, to demonstrate that the major cytogenetic response or peripheral blood BCR-ABL level of less than 1% has been sustained.

For each authority application where eligibility for continuing PBS-subsidised treatment is to be demonstrated, a copy of the cytogenetic analysis indicating the number of Philadelphia positive [t (9;22)] cells in the bone marrow measured by standard karyotyping, or a copy of the quantitative PCR indicating the relative level of BCR-ABL transcript in the peripheral blood using the international scale, must be submitted as described in (i) and (ii) above. For bone marrow analyses, where the standard karyotyping conducted at the time of application is not informative, a copy of a cytogenetic analysis conducted on the bone marrow using FISH with BCR-ABL specific probe must be submitted with the authority application. A copy of the non-informative standard karyotype analysis must be included with the authority application.

Where a patient has previously received PBS-subsidised treatment with dasatinib, no approval will be granted for PBS-subsidised re-treatment where that patient has at any time failed to meet the criteria for continuing treatment.

9089J **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)

8637N **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

8861J **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

Authority required

Initial 1 (new patients)
Application for initial PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have severe active rheumatoid arthritis; and
(b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and
(c) have failed to achieve an adequate response to the following treatments:
(i) methotrexate at a dose of at least 20 mg weekly; and
(ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and
(iii) a minimum of 3 months' treatment with:
— leflunomide alone; or
— leflunomide in combination with methotrexate; or
— cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;
AND either
(i) a total active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list of major joints:

— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and
(3) a signed patient acknowledgement.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks 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).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with etanercept.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Authority required

Initial 2 (change or re-commencement)
Application for an initial course of PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:
(a) have a documented history of severe active rheumatoid arthritis; and
(b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with etanercept within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment, within the timeframes specified below.

A maximum of 16 weeks of treatment will be authorised under this restriction.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 16 weeks 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).

Where the most recent course of PBS-subsidised etanercept treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised etanercept treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Authority required

Initial treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years; AND
(a) who have signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of PBS-subsidised treatment; AND
(b) who have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly; AND
(c) who have failed to achieve an adequate response to methotrexate, in combination with 2 other disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; AND
(d) who have subsequently failed to achieve an adequate response following a minimum of 3 months' treatment with:
(i) leflunomide alone; or
(ii) leflunomide in combination with methotrexate; or
(iii) cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, or intolerance of a severity necessitating permanent treatment withdrawal develops during the relevant period of use, the patient is exempted from demonstrating an inadequate response to the above treatment regimens. Details of the contraindication or intolerance, including the degree of toxicity, must be provided at the time of application.

The following criteria must be met in order to demonstrate failure to achieve an adequate response:
an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either
(i) an active joint count of at least 20 active (swollen and tender) joints; or
(ii) at least 4 active joints from the following list:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be in writing and must include sufficient information to determine the patient's eligibility according to the above criteria. The date of joint assessment must be provided.

Where fewer than 3 repeats are requested at the time of the initial authority application, authority approvals for sufficient repeats to complete a maximum of 4 months of treatment may be requested by telephone. Under no circumstances will telephone approvals be granted for initial or continuing authority applications, or for treatment that would otherwise extend the initial treatment period beyond 4 months.

The assessment of the patient's response to the initial course of treatment should be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. Applications for continuing treatment with etanercept should be made prior to the completion of 16 weeks of treatment to ensure continuity for those patients who meet the criteria

9090K **Etanercept**, Injections 50 mg in 1 mL single use pre-filled syringes, 4 (*Enbrel*)
8638P **Etanercept**, Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)
8862K **Etanercept**, Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL (*Enbrel*)

Authority required

Continuing treatment
Continuing PBS-subsidised treatment with etanercept, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:
(a) who have a documented history of severe active rheumatoid arthritis; and
(b) who have demonstrated an adequate response to treatment with etanercept; and
(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with etanercept.

An adequate response to treatment is defined as:
an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;
AND either of the following:
(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks 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).

All applications for continuing treatment with etanercept must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with etanercept, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with etanercept under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial etanercept after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Authority required

Initial PBS-subsidised supply for continuing treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented

history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years, and who were receiving treatment with etanercept prior to 1 December 2002; AND
(a) who have signed a patient agreement form indicating that they understand and acknowledge that PBS-subsidised treatment will cease if the predetermined response criteria do not support continuation of PBS-subsidised treatment; AND
(b) who have demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with etanercept.

The authority application must be in writing and must include sufficient information to determine the patient's eligibility. The date of assessment of the patient must be provided

Authority required

Continuing PBS-subsidised treatment, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of patients aged 18 years or older with a documented history of severe active polyarticular course juvenile chronic arthritis with onset prior to the age of 18 years, who, at the time of application, demonstrate an adequate response to treatment with etanercept as manifested by: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND 1 or more of the following:
(i) an active joint count of fewer than 10 active (swollen and tender) joints; or
(ii) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
(iii) a reduction in the number of the following active joints, from at least 4, by at least 50%:
— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
— shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All authority applications for continuing treatment with etanercept must be in writing and must include sufficient information to determine the patient's response according to the above criteria. The date of assessment of the patient must be provided.

Patients who fail to demonstrate an adequate response, as specified in the criteria for continuing treatment with etanercept, will not be eligible to recommence treatment with etanercept within 12 months of the date on which treatment was ceased.

Where re-treatment with etanercept after a break in PBS-subsidised treatment with the drug is being sought, the reason for and date of cessation of the previous treatment course with etanercept must be included in the application

8757X **Ezetimibe**, Tablet 10 mg (*Ezetrol*)

Authority required (STREAMLINED)

Treatment, in conjunction with dietary therapy and exercise, for co-administration with an HMG CoA reductase inhibitor (statin) in patients whose cholesterol levels are inadequately controlled with a statin and who have

2649

(a) coronary heart disease

2650

(b) diabetes mellitus

2651

(c) peripheral vascular disease

2652

(d) heterozygous familial hypercholesterolaemia

2653

(e) symptomatic cerebrovascular disease

2667

(f) family history of coronary heart disease

2268

(g) hypertension

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy, a cholesterol level in excess of that threshold after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level, a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated

1989

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) is contraindicated

2669

Patients eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs) where treatment with an HMG CoA reductase inhibitor (statin) must be discontinued or reduced to a dose of 20 mg or less per day, because the patient developed a clinically important product-related adverse event during treatment with a statin.

A clinically important product-related adverse event is defined as follows:

(i) Severe myalgia (muscle symptoms without CK elevation) which is proven to be temporally associated with statin treatment; or

(ii) Myositis (clinically important CK elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or

(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin

Authority required (STREAMLINED)

1991

Homozygous sitosterolaemia

2438

Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), in combination with an HMG CoA reductase inhibitor (statin)

8881K **Ezetimibe with simvastatin**, Tablet 10 mg-40 mg (*Vytorin*)
8882L **Ezetimibe with simvastatin**, Tablet 10 mg-80 mg (*Vytorin*)

Authority required (STREAMLINED)

Treatment, in conjunction with dietary therapy and exercise, in patients whose cholesterol levels are inadequately controlled with an HMG CoA reductase inhibitor (statin) and who have

2654

(a) coronary heart disease

2655

(b) diabetes mellitus

2656

(c) peripheral vascular disease

2657

(d) heterozygous familial hypercholesterolaemia

2658

(e) cerebrovascular disease which has become symptomatic

2678

(f) family history of coronary heart disease

2679

(g) hypertension

Inadequate control with a statin is defined as follows:

(1) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy, a cholesterol level in excess of that threshold after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when the ezetimibe component is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when the ezetimibe component is initiated; or

(2) where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level, a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a daily dose of 40 mg or greater of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when the ezetimibe component is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when the ezetimibe component is initiated

2431

Patients with homozygous familial hypercholesterolaemia who are eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs)

8519J **Fluticasone propionate with salmeterol xinafoate**, Oral pressurised inhalation 250 micrograms-25 micrograms (base) per dose (120 doses), CFC-free formulation (*Seretide MDI 250/25*)
8432T **Fluticasone propionate with salmeterol xinafoate**, Powder for oral inhalation in breath actuated device 500 micrograms-50 micrograms (base) per dose (60 doses) (*Seretide Accuhaler 500/50*)

Restricted benefit

Patients who previously had frequent episodes of asthma while receiving treatment with oral corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate

Restricted benefit

Patients who previously had frequent episodes of asthma while receiving treatment with optimal doses of inhaled corticosteroids and who have been stabilised on concomitant inhaled salmeterol xinafoate and fluticasone propionate

Restricted benefit

Symptomatic treatment of chronic obstructive pulmonary disease (COPD), where the FEV1 is less than 50% predicted normal and there is a history of repeated exacerbations with significant symptoms despite regular beta-2 agonist bronchodilator therapy

6397Q **Infliximab**, Powder for I.V. infusion 100 mg (*Remicade*)

Public and private hospital authority required

Initial 1 (new patients)

Application for initial PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have severe active rheumatoid arthritis; and

(b) have received no prior PBS-subsidised treatment with a bDMARD for this condition in this treatment cycle; and

(c) have failed to achieve an adequate response to the following treatments:

(i) methotrexate at a dose of at least 20 mg weekly; and

(ii) methotrexate (at a minimum dose of 7.5 mg weekly), in combination with 2 other non-biological disease modifying anti-rheumatic drugs (DMARDs), for a minimum of 3 months; and

(iii) a minimum of 3 months' treatment with:— leflunomide alone; or— leflunomide in combination with methotrexate; or— cyclosporin.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities, including severity, can be found on the Medicare Australia website [www.medicareaustralia.gov.au].

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

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L;

AND either

(i) a total active joint count of at least 20 active (swollen and tender) joints; or

(ii) at least 4 active joints from the following list of major joints:— elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or— shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)] which includes

details of the patient's ESR and CRP measurements and the patient's active joint count which must have been assessed no earlier than 1 month prior to the date of application; and

(3) a signed patient acknowledgement.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks 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).

Assessment of a patient's response to an initial course of treatment must be made after at least 12 weeks of treatment so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Public and private hospital authority required

Initial 2 (change or re-commencement)

Application for an initial course of PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults who:

(a) have a documented history of severe active rheumatoid arthritis; and

(b) have received prior PBS-subsidised bDMARD treatment for this condition in this treatment cycle and are eligible to receive further bDMARD therapy.

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

Applications for patients who have received PBS-subsidised treatment with infliximab within this treatment cycle and who wish to re-commence therapy with this drug within this same cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised infliximab treatment, within the timeframes specified below.

A maximum of 22 weeks of treatment will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 3 repeats may be authorised.

Where fewer than 3 repeats are requested at the time of the initial application, authority approvals for sufficient repeats to complete a maximum of 22 weeks 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).

Where the most recent course of PBS-subsidised infliximab treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised bDMARD therapy or, under

this restriction, for patients who have received previous PBS-subsidised bDMARD therapy), patients must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where the most recent course of PBS-subsidised infliximab treatment was approved under the continuing treatment criteria, patients must have been assessed for response, and the assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

Public and private hospital authority required

Continuing treatmentContinuing PBS-subsidised treatment with infliximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of adults:

(a) who have a documented history of severe active rheumatoid arthritis; and

(b) who have demonstrated an adequate response to treatment with infliximab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this treatment cycle was with infliximab.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)].

A maximum of 24 weeks of treatment will be approved under this restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 3 mg per kg. Up to a maximum of 2 repeats may be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks 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).

All applications for continuing treatment with infliximab must include a measurement of response to the prior course of therapy. This assessment must be provided to Medicare Australia no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with infliximab, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with an initial treatment course.

Patients who fail to demonstrate a response to treatment with infliximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this treatment cycle. Patients may

re-trial infliximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this cycle and the date of the first application under the new cycle

8373Q **Leflunomide**, Pack containing 3 tablets leflunomide 100 mg and 30 tablets leflunomide 20 mg (*Arava*)

Authority required (STREAMLINED)

2643

Initial treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician

Authority required (STREAMLINED)

2681

Initial treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician

8374R **Leflunomide**, Tablet 10 mg (*Arabloc*, *Arava*)
8375T **Leflunomide**, Tablet 20 mg (*Arabloc*, *Arava*)

Authority required (STREAMLINED)

2644

Treatment of severe active rheumatoid arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician

Authority required (STREAMLINED)

2682

Treatment of severe active psoriatic arthritis where other disease modifying anti-rheumatic drugs (including methotrexate) are ineffective and/or inappropriate. Treatment must be initiated by a physician

8245Y **Letrozole**, Tablet 2.5 mg (*Femara 2.5 mg*)

Restricted benefit

Treatment of hormone-dependent advanced breast cancer in post-menopausal women

Restricted benefit

Treatment of hormone-dependent early breast cancer in post-menopausal women

Restricted benefit

Extended adjuvant treatment of hormone-dependent early breast cancer in post-menopausal women commencing within 6 months of ceasing treatment with tamoxifen citrate

8633J **Levonorgestrel**, Intrauterine drug delivery system 52 mg (releasing approximately 20 micrograms per 24 hours) (*Mirena*)

Restricted benefit

Contraception

Restricted benefit

Idiopathic menorrhagia where oral treatments are ineffective

Restricted benefit

Idiopathic menorrhagia where oral treatments are contraindicated

8612G **Macrogol 3350**, Sachets containing powder for solution 13.125 g with electrolytes, 30 *(Movical)*

Restricted benefit

Paraplegic and quadriplegic patients and others with severe neurogenic impairment of bowel function not responding to other oral therapies

2234N **Mesalazine**, Sachet containing prolonged release granules, 1 g per sachet (*Pentasa*)
2287J **Mesalazine**, Sachet containing prolonged release granules, 2 g per sachet (*Pentasa*)
2214M **Mesalazine**, Tablet 500 mg (prolonged release) (*Pentasa*)

Authority required (STREAMLINED)

1708

Ulcerative colitis where hypersensitivity to sulfonamides exists

Authority required (STREAMLINED)

1709

Ulcerative colitis where intolerance to sulfasalazine exists

Authority required (STREAMLINED)

2268

Crohn's disease where hypersensitivity to sulfonamides exists

Authority required (STREAMLINED)

2269

Crohn's disease where intolerance to sulfasalazine exists

2172H **Methylphenidate hydrochloride**, Tablet 27 mg (extended release) (*Concerta*)

Authority required

Treatment of attention deficit hyperactivity disorder (ADHD) in a patient aged 6 to 18 years inclusive, who has demonstrated a response to immediate release methylphenidate hydrochloride with no emergence of serious adverse events, and who requires continuous coverage over 12 hours

2626F **Ramipril with felodipine**, Tablet 2.5 mg-2.5 mg (modified release) (*Triasyn 2.5/2.5*)
2629J **Ramipril with felodipine**, Tablet 5 mg-5 mg (modified release) (*Triasyn 5.0/5.0*)

Restricted benefit

Hypertension in a patient not adequately controlled with either ramipril or felodipine monotherapy

1371E **Ranibizumab**, Solution for intravitreal injection 3 mg in 0.3 mL (*Lucentis*)

Authority required

Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:

(a) a completed authority prescription form; and

(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and

(c) a copy of the fluorescein angiogram.

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

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Alternatively, the first authority application may be faxed to Medicare Australia on (03) 6215 5474 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained

1382R **Ranibizumab**, Solution for intravitreal injection 3 mg in 0.3 mL (*Lucentis*)

Authority required

Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD) where the patient has previously been granted an authority prescription for the same eye.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

8621R **Risedronate sodium**, Tablet 35 mg (*Actonel Once-a-Week*)

8481J **Risedronate sodium**, Tablet 5 mg (*Actonel*)

8899J **Risedronate sodium and calcium carbonate**, Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium carbonate 1.25 g (equivalent to 500 mg calcium) (*Actonel Combi*)

Authority required (STREAMLINED)

2645

Treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in a patient aged 70 years of age or older with a Bone Mineral Density (BMD) T-score of -3.0 or less.

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

Authority required (STREAMLINED)

2646

Treatment as the sole PBS-subsidised anti-resorptive agent for established osteoporosis in patients with fracture due to minimal trauma. The fracture must have been demonstrated radiologically and the year of plain x-ray or CT-scan or MRI scan must be documented in the patient's medical records when treatment is initiated.

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

Note:

Anti-resorptive agents in established osteoporosis include alendronate sodium, risedronate sodium, disodium etidronate, raloxifene hydrochloride and strontium ranelate.

9611W **Rituximab**, Solution for I.V. infusion 500 mg in 50 mL (*Mabthera*)

Public and private hospital authority required

Initial 2 (change or re-commencement)

Application for an initial course of PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult who:

(a) has a documented history of severe active rheumatoid arthritis; and

(b) has failed to respond to at least 1 PBS-subsidised TNF-alfa antagonist in this Treatment Cycle; and

(c) has not previously failed to respond to PBS-subsidised rituximab in the current Treatment Cycle.

Applications for patients who have demonstrated a response to PBS-subsidised rituximab treatment within this Treatment Cycle and who wish to re-commence rituximab treatment within the same Cycle following a break in therapy, will only be approved where evidence of a response to the patient's most recent course of PBS-subsidised rituximab treatment has been submitted to Medicare Australia.

A patient may qualify to receive a further course of treatment (1 infusion at week 0 and 1 infusion at week 2) every 24 weeks with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial application must be used for assessment of all continuing applications.

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

Patients who fail to demonstrate a response to treatment with rituximab under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug, in this Treatment Cycle. Patients may re-trial rituximab after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.

Patients who fail to demonstrate a response to rituximab treatment and who qualify to trial an alternate bDMARD according to the interchangeability arrangements for bDMARDs for the treatment of severe rheumatoid arthritis, may do so without having to have a 22 week treatment-free period.

Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle

Public and private hospital authority required

Initial 3 ('grandfather' patients)

Initial PBS-subsidised supply for continuing treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult who:

(a) has a documented history of severe active rheumatoid arthritis; and

(b) was receiving treatment with rituximab prior to 7 March 2007; and

(c) has demonstrated a response as specified in the criteria for continuing PBS-subsidised treatment with rituximab.

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au] which includes the signed patient acknowledgement form.

The same indices of disease severity used to establish baseline at the commencement of treatment with a bDMARD must be used for assessment of all continuing applications.

Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.

Patients can qualify for PBS-subsidised treatment under this criteria once only.

Public and private hospital authority required

Continuing treatment

Continuing PBS-subsidised treatment with rituximab, in combination with methotrexate at a dose of at least 7.5 mg weekly, by a rheumatologist or clinical immunologist with expertise in the management of rheumatoid arthritis, of an adult:

(a) who has a documented history of severe active rheumatoid arthritis; and

(b) who has demonstrated an adequate response to treatment with rituximab; and

(c) whose most recent course of PBS-subsidised bDMARD treatment in this Treatment Cycle was with rituximab.

An adequate response to treatment is defined as:

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

AND either of the following:

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

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

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

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

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

(1) a completed authority prescription form; and

(2) a completed Rheumatoid Arthritis PBS Authority Application - Supporting Information Form [www.medicareaustralia.gov.au].

Patients may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction. The demonstration of response must be submitted to Medicare Australia within 4 weeks of assessment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial application must be used for assessment of all continuing applications.

Patients who fail to demonstrate a response to treatment with 3 bDMARDs are deemed to have completed this Treatment Cycle and must cease PBS-subsidised therapy. These patients may re-commence a new bDMARD Treatment Cycle after a minimum of 5 years has elapsed between the date the last prescription for a PBS-subsidised bDMARD was approved in this Cycle and the date of the first application under the new Cycle.

2700D **Thyrotropin alfa**, Powder for injection 0.9 mg, 2 (*Thyrogen*)

Authority required

Ablation of thyroid remnant tissue, in combination with radioactive iodine, in a post thyroidectomy adult aged 18 years or older without known metastatic disease. This drug is only PBS-subsidised for 1 treatment in a patient's lifetime

9610T **Tipranavir**, Capsule 250 mg (*Aptivus*)

Private hospital authority required

Treatment, in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily, of HIV infection in antiretroviral experienced adults with:

(a) evidence of HIV replication (viral load greater than 10,000 copies per mL); and/or

(b) CD4 cell counts of less than 500 per cubic millimetre.

Patients must have failed previous treatment with, or have resistance to, 3 different antiretroviral regimens which have included:

(i) at least 1 non-nucleoside reverse transcriptase inhibitor; and

(ii) at least 1 nucleoside reverse transcriptase inhibitor; and

(iii) at least 2 protease inhibitors

9057Q **Travoprost with timolol maleate**, Eye drops 40 micrograms-5 mg (base) per mL (0.004%-0.5%), 2.5 mL (*Duotrav*)

Restricted benefit

Reduction of elevated intra-ocular pressure in patients with open-angle glaucoma who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops or travoprost eye drops

Restricted benefit

Reduction of elevated intra-ocular pressure in patients with ocular hypertension who are not adequately controlled with timolol maleate 5 mg (base) per mL (0.5%) eye drops or latanoprost eye drops or travoprost eye drops

1349B **Verteporfin**, Powder for I.V. infusion 15 mg (*Visudyne*)

Authority required

Initial treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to age-related macular degeneration (AMD), as diagnosed by fluorescein angiography, in a patient with a baseline visual acuity equal to or better than 6/60 (20/200).

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:
(a) a completed authority prescription form; and
(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au]; and
(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

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

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Alternatively, the first authority application may be faxed to Medicare Australia on (03) 6215 5474 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.

No more than 15 treatments (1 initial and 14 continuing) per eye will be authorised.

Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum

Authority required

Initial PBS-subsidised treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has been authorised by the Angiogram Review Panel to receive treatment with verteporfin in the same eye under the MBS Visudyne Therapy Program.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia.

The first authority application for each eye must be made in writing, and must include:
(a) a completed authority prescription form; and
(b) a completed Subfoveal Choroidal Neovascularisation (CNV) - PBS Supporting Information Form [www.medicareaustralia.gov.au], which includes the date of review by the Angiogram Review Panel and the number of treatments administered in that eye under the MBS Visudyne Therapy Program; and
(c) a copy of the fluorescein angiogram demonstrating that the CNV is predominantly classic (greater than or equal to 50%).

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

Medicare Australia
Prior Written Approval of Specialised Drugs
Reply Paid 9826
GPO Box 9826
HOBART TAS 7001

Alternatively, the first authority application may be faxed to Medicare Australia on (03) 6215 5474 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Medicare Australia will then contact the prescriber by telephone. The original documentation must be posted to the above address after approval has been gained.

A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum

Authority required

Continuing treatment by an ophthalmologist, as the sole PBS-subsidised therapy, of predominantly (greater than or equal to 50%) classic, subfoveal choroidal neovascularisation (CNV) due to macular degeneration where the patient has previously been granted an authority prescription for the same eye.

A patient is eligible for a total of 15 subsidised treatments per eye. This maximum includes treatments administered under the MBS Visudyne Therapy Program and the PBS.

Medicare Australia should be notified if treatment is abandoned prior to completion of the laser activation step but after infusion of verteporfin. Telephone 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). The reason treatment is abandoned must be provided. Where such notification has been made, the treatment so affected will not count towards the maximum.

Authority approvals will be administered by the PBS and Specialised Drugs Branch of Medicare Australia. Authority applications for continuing treatment in the same eye may be made by telephone on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

NOTES

The text of notes mentioned above:

Adalimumab

Anakinra

Etanercept

Infliximab

Rituximab

Note:

TREATMENT OF ADULT PATIENTS WITH SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological disease modifying anti-rheumatic drugs (bDMARDs) for adults with severe active rheumatoid arthritis. Where the term bDMARD appears in the following notes and restrictions it refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, etanercept, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab) and the interleukin-1 inhibitor (anakinra).

Patients are eligible for PBS-subsidised treatment with only 1 of the above biological disease modifying anti-rheumatic drugs at any 1 time.

PBS-subsidised infliximab, anakinra and rituximab must be used in combination with methotrexate at a dose of at least 7.5 mg weekly. Where a patient cannot tolerate 7.5 mg of methotrexate weekly, they are only eligible to receive PBS-subsidised etanercept and adalimumab.

In order to be eligible to receive PBS-subsidised treatment with rituximab, a patient must have already failed to demonstrate a response to at least 1 course of treatment with a PBS-subsidised TNF-alfa antagonist.

From 1 August 2007, under the PBS, all patients will be able to commence a Treatment Cycle where they may trial PBS-subsidised bDMARD agents without having to experience a disease flare when swapping to an alternate agent. Under these interchangeability arrangements, within a single Treatment Cycle, a patient may continue to receive long-term treatment with a bDMARD while they continue to show a response to therapy.

A patient who received PBS-subsidised bDMARD treatment prior to 1 August 2007 is considered to be in their first Cycle as of 1 August 2007.

Within the same Treatment Cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised bDMARD more than once.

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

For patients who have failed PBS-subsidised treatment with 3 bDMARDs prior to 1 August 2007 please contact Medicare Australia on 1800 700 270.

The 5-year break is measured from the date of the last approval for PBS-subsidised bDMARD treatment in the most recent Cycle to the date of the first application for initial treatment with a bDMARD under the new Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same Treatment Cycle.

A patient who has failed fewer than 3 bDMARDs in a Treatment Cycle and who has a break in therapy of more than 5 years, may commence a new Treatment Cycle.

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

If patients fail to respond to a particular bDMARD within a single Treatment Cycle, they are not eligible to receive further PBS-subsidised treatment with that drug until they commence the next Cycle.

(1) How to prescribe PBS-subsidised bDMARD therapy after 1 August 2007.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised bDMARD treatment in this Treatment Cycle and wishes to commence such therapy, excluding rituximab (Initial 1); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) bDMARD therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific bDMARD following a break in PBS-subsidised therapy with that agent (Initial 2).

Initial treatment authorisations will be limited to provide a maximum of 16 weeks of therapy for etanercept, adalimumab and anakinra, 22 weeks of therapy for infliximab and 2 infusions of rituximab.

From 1 August 2007, a patient must be assessed for response to any course of initial PBS-subsidised treatment (excluding rituximab) following a minimum of 12 weeks of therapy and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients must be assessed following a minimum of 12 weeks after the first infusion, and this assessment must be submitted to Medicare Australia within 4 weeks.

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 that bDMARD.

For second and subsequent courses of PBS-subsidised bDMARD (excluding rituximab) 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 submitted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Rituximab patients:

A further application may be submitted to Medicare Australia 24 weeks after the first infusion. New baselines may be submitted with this application if appropriate.

(b) Continuing treatment.

Following the completion of an initial treatment course with a specific bDMARD (excluding rituximab), a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing bDMARD treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted bDMARD supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Rituximab patients:

A patient may qualify to receive a further course of treatment (every 24 weeks) with this agent providing they have demonstrated an adequate response to treatment following a minimum of 12 weeks after the first infusion of their most recent treatment with rituximab. The patient remains eligible to receive a course of rituximab every 24 weeks providing they continue to demonstrate a response as specified in the restriction.

Where a response assessment is not submitted to Medicare Australia within these time frames, the patient will be deemed to have failed to respond to treatment with that bDMARD.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised bDMARD is approved, a patient may swap to an alternate bDMARD within the same Treatment Cycle without having to requalify with respect to the indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the joint count) or the prior non-bDMARD therapy requirements. However the requirement for concomitant treatment with methotrexate, where it applies, must be met for each bDMARD trialled.

Patients who are not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that agent.

A patient may trial an alternate bDMARD at any time, regardless of whether they are receiving therapy (initial or continuing) with a bDMARD at the time of the application. However, they cannot swap to a particular bDMARD if they have failed to respond to prior treatment with that drug within the same Treatment Cycle.

In order to trial rituximab, a patient must have trialled and failed to demonstrate a response to at least 1 PBS-subsidised TNF-alfa antagonist treatment.

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

PBS subsidy does not allow for patients to receive treatment with another PBS-subsidised biological agent during the required treatment-free period applying to patients who have demonstrated a response to their most recent course of rituximab. This means that patients who have demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate bDMARD. Patients who fail to respond to rituximab and who qualify and wish to trial a course of an alternate bDMARD may do so without having to have any treatment-free period.

To avoid confusion, an application for a patient who wishes to swap to an alternate bDMARD should be accompanied by the approved authority prescription or remaining repeats for the bDMARD the patient is ceasing.

(3) Baseline measurements to determine response.

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the joint count, ESR and/or CRP submitted with the first authority application for a bDMARD. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a Treatment Cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be provided to determine response.

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

A patient who wishes to trial a second or subsequent Treatment Cycle following a break in PBS-subsidised bDMARD therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with at least 1 non-biological DMARD, at an adequate dose, for a minimum of 3 months at the time the ESR and/or CRP levels and the active joint count are measured.

(5) Patients 'grandfathered' onto PBS-subsidised treatment with rituximab.

From 1 August 2007, a patient who commenced treatment with rituximab for severe rheumatoid arthritis prior to 7 March 2007 and who was 'grandfathered' on to PBS-subsidised therapy, and who continues to receive treatment in the same Treatment Cycle, will have further applications for treatment with rituximab assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first Treatment Cycle. For the second and subsequent Cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that applies to a new

patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

Amlodipine

Note:

Bioequivalence has been demonstrated between the tablet containing 5 mg amlodipine (as besylate) and the tablet containing 5 mg amlodipine (as maleate).

Note:

Bioequivalence has been demonstrated between the tablet containing 10 mg amlodipine (as besylate) and the tablet containing 10 mg amlodipine (as maleate).

8750M **Budesonide with eformoterol fumarate dihydrate**, Powder for oral inhalation in breath actuated devices 400 micrograms-12 micrograms per dose (60 doses), 2 (*Symbicort Turbuhaler 400/12*)

Note:

Symbicort 400/12 is not recommended nor PBS-subsidised for use as 'maintenance and reliever' therapy.

Dihydropyridine derivatives

Note:

The base-priced drugs in this therapeutic group are amlodipine, felodipine and nifedipine (except nifedipine controlled release tablet 20 mg).

Diphtheria and tetanus vaccine, adsorbed, diluted for adult use

Note:

For immunisation of adults and children aged greater than or equal to 8 years.

8519J **Fluticasone propionate with salmeterol xinafoate**, Oral pressurised inhalation 250 micrograms-25 micrograms (base) per dose (120 doses), CFC-free formulation (Seretide MDI 250/25)

8432T **Fluticasone propionate with salmeterol xinafoate**, Powder for oral inhalation in breath actuated device 500 micrograms-50 micrograms (base) per dose (60 doses) (Seretide Accuhaler 500/50)

Note:

Seretide is not indicated for the initiation of bronchodilator therapy in COPD.

Letrozole

Note:

This drug is not PBS-subsidised for primary prevention of breast cancer.

This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.

This drug is not PBS-subsidised for extended adjuvant early breast cancer treatment where the total duration of letrozole (or any other aromatase inhibitor) treatment extends beyond 5 years.

Perindopril with indapamide hemihydrate

Note:

Bioequivalence has been demonstrated between perindopril erbumine/indapamide hemihydrate tablet 4 mg-1.25 mg and perindopril arginine/indapamide hemihydrate tablet 5 mg-1.25 mg.

Tipranavir

Note:

This price is based on special supply arrangements—see Pharmaceutical Benefits Pricing Authority relativity sheet for full details.

REPATRIATION PHARMACEUTICAL BENEFITS

This Schedule is effective from 1 August 2007 and all previous issues are cancelled.

New Schedules take effect on the first day of each month.

SUMMARY OF CHANGES

ALTERATIONS

Alterations - Proprietary Name

From:
4122Y **Skin emollient**, Bath oil 500 mL, *Hamilton Bath Oil*
To:
4122Y **Skin emollient**, Bath oil 500 mL, *Hamilton Skin Therapy Oil*

From:
4549K **Skin cleanser**, Lotion 500 mL, *Hamilton Body Wash*
To:
4549K **Skin cleanser**, Lotion 500 mL, *Hamilton Skin Therapy Wash*

From:
4546G **Sunscreens**, Lotion (non-alcoholic) 125 mL, *Hamilton Broad Spectrum Milky Lotion 15+*
To:
4546G **Sunscreens**, Lotion (non-alcoholic) 125 mL, *Hamilton Sunscreen Family Sunscreen Milk SPF 15*

From:
4544E **Sunscreens**, Cream 100 g, *Hamilton Sunscreen Broad Spectrum Cream 15+*
To:
4544E **Sunscreens**, Cream 100 g, *Hamilton Sunscreen Family Sunscreen Cream SPF 15*