Australian Government

Department of Health and Ageing

SCHEDULE OF PHARMACEUTICAL BENEFITS

SUMMARY OF CHANGES

EFFECTIVE 1 DECEMBER 2009

PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 December 2009. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 December 2009 and are included, where applicable, in prices published in the Schedule—

Dispensing Fees:	Ready-prepared	$6.42
	Dangerous drug fee	$2.71
	Extemporaneously-prepared	$8.46
	Allowable additional patient charge*	$3.79
Additional Fees (for safety net prices):	Ready-prepared	$1.05
	Extemporaneously-prepared	$1.38
Patient Co-payments:	General	$32.90
	Concessional	$5.30
Safety Net Thresholds:	General	$1264.90
	Concessional	$318.00
Safety Net Card Issue Fee:		$8.25

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

SUMMARY OF CHANGES

ADDITIONS

Additions — Items

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

9499Y **Amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexanoic acid**, Oral liquid 125 mL, 36 (*MSUD Anamix Junior LQ*)

9498X **Artemether with lumefantrine**, Tablet 20 mg-120 mg (*Riamet*)

9494Q **Calcipotriol with betamethasone dipropionate**, Ointment 50 micrograms-500 micrograms (base) per g (0.005%-0.05%), 30 g (*Daivobet*)

3117C **Calcium**, Tablet 600 mg (as carbonate) (*Calci-Tab 600*)

9296G **Clopidogrel with aspirin**, Tablet 75 mg (as hydrogen sulfate)-100 mg (*CoPlavix, DuoCover*)

9485F **Glucose indicator—blood**, Reagent strips, 50 (*Lifeline Attest*)

9486G **Glucose indicator—blood**, Reagent strips, 50 (*Lifeline Attest*) **(Diff. Max. Rpts)**

9487H **Hydroxyethyl starch 130/0.4**, I.V. infusion 30 g per 500 mL, 500 mL (*Voluven 6%*)

9294E **Olanzapine**, Powder for injection 210 mg (as pamoate monohydrate) with diluent (*Zyprexa Relprevv*)

9295F **Olanzapine**, Powder for injection 300 mg (as pamoate monohydrate) with diluent (*Zyprexa Relprevv*)

9491M **Polyethylene glycol 400**, Eye drops 2.5 mg per mL (0.25%), 15 mL (*Blink Intensive Tears*)

9492N **Polyethylene glycol 400**, Eye drops 2.5 mg per mL (0.25%), 15 mL (*Blink Intensive Tears*) **(Diff. Max. Rpts)**

9493P **Polyethylene glycol 400**, Eye drops 2.5 mg per mL (0.25%), single dose units 0.4 mL, 20 (*Blink Intensive Tears*)

5559N **Polyethylene glycol 400**, Eye drops 2.5 mg per mL (0.25%), 15 mL (*Blink Intensive Tears*) **(Optometrical)**

5560P **Polyethylene glycol 400**, Eye drops 2.5 mg per mL (0.25%), single dose units 0.4 mL, 20 (*Blink Intensive Tears*) **(Optometrical)**

9495R **Prasugrel**, Tablet 5 mg (as hydrochloride) (*Effient*)

9496T **Prasugrel**, Tablet 10 mg (as hydrochloride) (*Effient*)

9488J **Sunitinib**, Capsule 12.5 mg (as malate) (*Sutent*) **(Diff. Restriction)**

9489K **Sunitinib**, Capsule 25 mg (as malate) (*Sutent*) **(Diff. Restriction)**

9490L **Sunitinib**, Capsule 50 mg (as malate) (*Sutent*) **(Diff. Restriction)**

Additions — Brands

1299J *APO-Diclofenac, TX* — **Diclofenac sodium**, Tablet 25 mg (enteric coated)

5361E *APO-Diclofenac, TX* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Palliative Care)**

5364H *APO-Diclofenac, TX* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Palliative Care) (Diff. Max. Rpts)**

5076E *APO-Diclofenac, TX* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Dental)**

9474P *Glucose 5% Freeflex, PK* — **Glucose**, I.V. infusion 69.5 mmol (anhydrous) per 250 mL (5%), 250 mL

8414W *Irinotecan Alphapharm, AF* — **Irinotecan hydrochloride trihydrate**, I.V. injection 40 mg in 2 mL

8415X *Irinotecan Alphapharm, AF* — **Irinotecan hydrochloride trihydrate**, I.V. injection 100 mg in 5 mL

1970Q *Quinapril-GA, GM* — **Quinapril hydrochloride**, Tablet 20 mg (base)

2012X *Simvastatin-GA 20, GN* — **Simvastatin**, Tablet 20 mg

9243L *Simvastatin-GA 20, GN* — **Simvastatin**, Tablet 20 mg **(Diff. Max. Rpts)**

8173E *Simvastatin-GA 40, GN* — **Simvastatin**, Tablet 40 mg

9244M *Simvastatin-GA 40, GN* — **Simvastatin**, Tablet 40 mg **(Diff. Max. Rpts)**

8313M *Simvastatin-GA 80, GN* — **Simvastatin**, Tablet 80 mg

9245N *Simvastatin-GA 80, GN* — **Simvastatin**, Tablet 80 mg **(Diff. Max. Rpts)**

9473N *Sodium Chloride 0.9% Freeflex, PK* — **Sodium chloride**, I.V. infusion 38.5 mmol per 250 mL (0.9%), 250 mL
2289L *Valprease 200, SI* — **Sodium valproate**, Tablet 200 mg (enteric coated)
2290M *Valprease 500, SI* — **Sodium valproate**, Tablet 500 mg (enteric coated)
8163P *Epiramax 25, SI* — **Topiramate**, Tablet 25 mg
8164Q *Epiramax 50, SI* — **Topiramate**, Tablet 50 mg
8165R *Epiramax 100, SI* — **Topiramate**, Tablet 100 mg
8166T *Epiramax 200, SI* — **Topiramate**, Tablet 200 mg
8582Q *Tramahexal, SZ* — **Tramadol hydrochloride**, Injection 100 mg in 2 mL
5231H *Tramahexal, SZ* — **Tramadol hydrochloride**, Injection 100 mg in 2 mL **(Dental)**
3484J *Tramahexal, SZ* — **Tramadol hydrochloride**, Injection 100 mg in 2 mL **(Doctor's Bag)**

Additions — Bioequivalence Indicators

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

9474P *B. Braun Australia Pty Ltd, BR* — **Glucose**, I.V. infusion 69.5 mmol (anhydrous) per 250 mL (5%), 250 mL
9473N *B. Braun Australia Pty Ltd, BR* — **Sodium chloride**, I.V. infusion 38.5 mmol per 250 mL (0.9%), 250 mL
8582Q *Tramal 100, CS* — **Tramadol hydrochloride**, Injection 100 mg in 2 mL
5231H *Tramal 100, CS* — **Tramadol hydrochloride**, Injection 100 mg in 2 mL **(Dental)**
3484J *Tramal 100, CS* — **Tramadol hydrochloride**, Injection 100 mg in 2 mL **(Doctor's Bag)**

DELETIONS

Deletions — Items

8291J **Calcipotriol**, Ointment 50 micrograms per g (0.005%), 30 g (*Daivonex*)
9194X **Paliperidone**, Tablet 12 mg (prolonged release) (*Invega*)
2248H **Tamarindus indica seed polysaccharide**, Eye drops 10 mg per mL (1%), 0.5 mL, 20 (*Visine Professional*)
5531D **Tamarindus indica seed polysaccharide**, Eye drops 10 mg per mL (1%), 0.5 mL, 20 (*Visine Professional*) **(Optometrical)**

Deletions — Brands

8115D *Tinexa, SI* — **Cabergoline**, Tablet 500 micrograms
8114C *Tinexa, SI* — **Cabergoline**, Tablet 500 micrograms **(Diff. Max. Qty and Rpts)**
1157X *Tagamet, GK* — **Cimetidine**, Tablet 200 mg
2242B *Paroxetine Winthrop, WA* — **Paroxetine**, Tablet 20 mg (as hydrochloride)
1975Y *Quinsul, LN* — **Quinine sulfate**, Tablet 300 mg
2237R *Sertraline Winthrop, WA* — **Sertraline hydrochloride**, Tablet 100 mg (base)

Deletions — Bioequivalence Indicators

The bioequivalence indicator (a) has been removed from the following brands:

8115D *Dostinex, PH* — **Cabergoline**, Tablet 500 micrograms
8114C *Dostinex, PH* — **Cabergoline**, Tablet 500 micrograms **(Diff. Max. Qty and Rpts)**
1157X *Magicul 200, AF* — **Cimetidine**, Tablet 200 mg
1975Y *Quinate, AS* — **Quinine sulfate**, Tablet 300 mg

ALTERATIONS

Alteration — Item Description

From:
8358X **Clopidogrel hydrogen sulfate**, Tablet 75 mg (base) (*Iscover, Plavix*)
To:
8358X **Clopidogrel**, Tablet 75 mg (as hydrogen sulfate) (*Iscover, Plavix*)

Alterations — Proprietary Name

From:
1472L **Fluconazole**, Capsule 100 mg (*Fluconazole Hexal*)
To:
1472L **Fluconazole**, Capsule 100 mg (*Fluconazole Sandoz*)

From:
1475P **Fluconazole**, Capsule 200 mg (*Fluconazole Hexal*)
To:
1475P **Fluconazole**, Capsule 200 mg (*Fluconazole Sandoz*)

From:
1746X **Paracetamol**, Tablet 500 mg (*Chem mart Chemadol*)
To:
1746X **Paracetamol**, Tablet 500 mg (*Chem mart Paracetamol*)

From:
8784H **Paracetamol**, Tablet 500 mg (*Chem mart Chemadol*) **(Diff. Max. Qty and Rpts)**
To:
8784H **Paracetamol**, Tablet 500 mg (*Chem mart Paracetamol)* **(Diff. Max. Qty and Rpts)**

From:
5196L **Paracetamol**, Tablet 500 mg (*Chem mart Chemadol*) **(Dental)**
To:
5196L **Paracetamol**, Tablet 500 mg (*Chem mart Paracetamol*) **(Dental)**

From:
5224Y **Paracetamol**, Tablet 500 mg (*Chem mart Chemadol*) **(Dental) (Diff. Max. Qty)**
To:
5224Y **Paracetamol**, Tablet 500 mg (*Chem mart Paracetamol*) **(Dental) (Diff. Max. Qty)**

Alterations — Manufacturer's Code

		From	*To*
1970Q	**Quinapril hydrochloride**, Tablet 20 mg (base) (*Quinapril-DP*)	GM	GN
2236Q	**Sertraline hydrochloride**, Tablet 50 mg (base) (*Xydep 50*)	AW	PU
8836C	**Sertraline hydrochloride**, Tablet 50 mg (base) (*Xydep 50*) **(Diff. Restriction)**	AW	PU
2237R	**Sertraline hydrochloride**, Tablet 100 mg (base) (*Xydep 100*)	AW	PU
8837D	**Sertraline hydrochloride**, Tablet 100 mg (base) (*Xydep 100*) **(Diff. Restriction)**	AW	PU

Alterations — Restrictions

(see under 'RESTRICTIONS' below for full details)

8628D **Montelukast sodium**, Chewable tablet 5 mg (base) (*Singulair*)
9151P **Pramipexole hydrochloride**, Tablet 125 micrograms (*Sifrol*)
9152Q **Pramipexole hydrochloride**, Tablet 250 micrograms (*Sifrol*)
9153R **Pramipexole hydrochloride**, Tablet 1 mg (*Sifrol*)

Alterations — Notes

(see under 'NOTES' below for full details)

8627C **Montelukast sodium**, Chewable tablet 4 mg (base) (*Singulair*)

8628D **Montelukast sodium**, Chewable tablet 5 mg (base) (*Singulair*)

SECTION 100

HIGHLY SPECIALISED DRUGS PROGRAM

ADDITIONS

Additions — Items

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

9648T **Ambrisentan**, Tablet 5 mg (*Volibris*)

9649W **Ambrisentan**, Tablet 10 mg (*Volibris*)

ALTERATIONS

Alterations — Restrictions

(see under 'RESTRICTIONS' below for full details)

9642L **Lenalidomide**, Capsule 5 mg (*Revlimid*)

9643M **Lenalidomide**, Capsule 10 mg (*Revlimid*)

9644N **Lenalidomide**, Capsule 15 mg (*Revlimid*)

9645P **Lenalidomide**, Capsule 25 mg (*Revlimid*)

6358P **Tenofovir disoproxil fumarate**, Tablet 300 mg (*Viread*)

Alterations — Notes

(see under 'NOTES' below for full details)

Bosentan Monohydrate

Epoprostenol Sodium
Iloprost Trometamol
Sildenafil Citrate

Sitaxentan Sodium

ADVANCE NOTICES

Advance Notice — Deletion of Items

The following items will be deleted from the Schedule of Pharmaceutical Benefits on 1 January 2010:

Items discontinued by the manufacturer—

2737C **Amino acid formula with vitamins and minerals without phenylalanine**, Infant formula, powder 400 g (*XP Analog*)

8706F **Amino acid formula without phenylalanine**, Bars 42 g, 20 (*Phlexy-10*)

Advance Notice — Deletion of Brands

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 January 2010:

Brands discontinued by the manufacturer—

8118G *Alprazolam-DP, GN* — **Alprazolam**, Tablet 2 mg

3161J *Ducene, SU* — **Diazepam**, Tablet 2 mg
3162K *Ducene, SU* — **Diazepam**, Tablet 5 mg
5357Y *Ducene, SU* — **Diazepam**, Tablet 2 mg **(Palliative Care)**
5355W *Ducene, SU* — **Diazepam**, Tablet 2 mg **(Palliative Care) (Diff. Max. Rpts)**
5358B *Ducene, SU* — **Diazepam**, Tablet 5 mg **(Palliative Care)**
5356X *Ducene, SU* — **Diazepam**, Tablet 5 mg **(Palliative Care) (Diff. Max. Rpts)**
5071X *Ducene, SU* — **Diazepam**, Tablet 2 mg **(Dental)**
5072Y *Ducene, SU* — **Diazepam**, Tablet 5 mg **(Dental)**

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 February 2010:

Brand discontinued by the manufacturer—

1300K *Dinac, GN* — **Diclofenac sodium**, Tablet 50 mg (enteric coated)

5365J *Dinac, GN* — **Diclofenac sodium**, Tablet 50 mg (enteric coated) **(Palliative Care)**
5362F *Dinac, GN* — **Diclofenac sodium**, Tablet 50 mg (enteric coated) **(Palliative Care) (Diff. Max. Rpts)**
5077F *Dinac, GN* — **Diclofenac sodium**, Tablet 50 mg (enteric coated) **(Dental)**

The following brands will be deleted from the Schedule of Pharmaceutical Benefits on 1 March 2010:

Brands discontinued by the manufacturer—

1299J *GenRx Diclofenac, GX* — **Diclofenac sodium**, Tablet 25 mg (enteric coated)

5364H *GenRx Diclofenac, GX* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Palliative Care)**
5361E *GenRx Diclofenac, GX* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Palliative Care) (Diff. Max. Rpts)**
5076E *GenRx Diclofenac, GX* — **Diclofenac sodium**, Tablet 25 mg (enteric coated) **(Dental)**
1147J *Acenorm 12.5 mg, AF* — **Captopril**, Tablet 12.5 mg
1148K *Acenorm 25 mg, AF* — **Captopril**, Tablet 25 mg
1149L *Acenorm 50 mg, AF* — **Captopril**, Tablet 50 mg

1970Q *Quinapril-DP, GN* — **Quinapril hydrochloride**, Tablet 20 mg (base)

The following brand will be deleted from the Schedule of Pharmaceutical Benefits on 1 April 2010:

Brand discontinued by the manufacturer—

3012M *K-Sol, LN* — **Potassium chloride with potassium bicarbonate**, Effervescent tablet 14 mmol potassium and 8 mmol chloride

RESTRICTIONS

The text of restrictions mentioned above:

Ambrisentan

CAUTION:

Ambrisentan is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of treatment with this drug.

NOTE:

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

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

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

NOTE:

Special Pricing Arrangements apply.

For additional note, see under 'NOTES' below.

9649W **Ambrisentan**, Tablet 10 mg (*Volibris*)

9648T **Ambrisentan**, Tablet 5 mg (*Volibris*)

Public and private hospital authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with ambrisentan of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure of 8 mmHg or less, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO.

Patients must have failed to respond [see Note for definition of response] to 6 or more weeks of appropriate vasodilator treatment unless intolerance or a contraindication to such treatment exists.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

Details of prior vasodilator treatment, including the dose and duration of treatment, must be provided at the time of application. Where the patient has an adverse event to a vasodilator or where vasodilator treatment is contraindicated, details on the nature of the adverse event or contraindication according to the TGA-approved Product Information must also be provided with the application.

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

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

Public and private hospital authority required

Initial (new patients)
Application for initial PBS-subsidised treatment with ambrisentan of patients who have not received prior PBS-subsidised treatment with a PAH agent and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease and a mean right atrial pressure greater than 8 mmHg, as measured by RHC, or, where a RHC cannot be performed on clinical grounds, right ventricular function as assessed by ECHO; OR
(c) WHO Functional Class IV primary pulmonary hypertension; OR
(d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) a signed patient and prescriber acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

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

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

Public and private hospital authority required

Initial (grandfather patients)
Application for initial PBS-subsidised treatment with ambrisentan of patients who were receiving treatment with ambrisentan prior to 1 December 2009 and who have been assessed by a physician from a designated hospital to have:
(a) WHO Functional Class III primary pulmonary hypertension; OR

(b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease; OR

(c) WHO Functional Class IV primary pulmonary hypertension; OR
(d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) for patients who have received less than 6 months of ambrisentan treatment at the time of application — a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results of the following 3 tests, where available, at the time treatment with ambrisentan was commenced:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT; and
(3) the date of commencement of ambrisentan treatment; and
(4) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment [see Note for definition of response].

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

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. The number of repeats authorised will be dependent on the duration of prior ambrisentan therapy. Where patients have received less than 6 months of non-PBS-subsidised treatment with ambrisentan, sufficient repeats to allow the patient to complete a total of 6 months of combined PBS-subsidised and non-PBS-subsidised therapy may be requested. Where fewer than the maximum allowable number of repeats are requested at the time of application, authority approvals for the remainder of the allowable repeats 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)

Public and private hospital authority required

Initial (change or re-commencement for all patients)
Application for initial treatment with ambrisentan of patients with one of the following:
(a) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who wish to re-commence PBS-subsidised ambrisentan after a break in therapy and who have demonstrated a response to their most recent course of PBS-subsidised treatment with ambrisentan; OR
(b) primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease and whose most recent course of PBS-subsidised treatment was with an alternate PAH agent other than ambrisentan.

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes the results on which approval for the first application for PBS-subsidised PAH agent was granted; and
(3) the date of the first application for PBS-subsidised treatment with a PAH agent; and
(4) the results of the patient's response to treatment with their last course of PBS-subsidised PAH agent.

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

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information. A maximum of 5 repeats may be requested. Where fewer than 5 repeats are requested at the time of application, authority

approvals for sufficient repeats to complete a maximum of 6 months of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

Public and private hospital authority required

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

Applications for authorisation must be in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Pulmonary Arterial Hypertension PBS Authority Application - Supporting Information form [www.medicareaustralia.gov.au] which includes results from the 3 tests below, where available:
(i) RHC composite assessment; and
(ii) ECHO composite assessment; and
(iii) 6MWT.

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

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

9499Y **Amino acid formula with vitamins and minerals without valine, leucine and isoleucine with fat, carbohydrate and trace elements and supplemented with docosahexanoic acid**, Oral liquid 125 mL, 36 (*MSUD Anamix Junior LQ*)

Restricted benefit

Maple syrup urine disease

9498X **Artemether with lumefantrine**, Tablet 20 mg-120 mg (*Riamet*)

Authority required

Treatment of suspected or confirmed malaria due to Plasmodium falciparum

NOTE:

Artemether with lumefantrine is not PBS-subsidised for prophylaxis of malaria.

9494Q **Calcipotriol with betamethasone dipropionate**, Ointment 50 micrograms-500 micrograms (base) per g (0.005%-0.05%), 30 g (*Daivobet*)

Restricted benefit

Chronic stable plaque type psoriasis vulgaris in a patient who is not adequately controlled with either calcipotriol or potent topical corticosteroid monotherapy

3117C **Calcium**, Tablet 600 mg (as carbonate) (*Calci-Tab 600*)

Authority required (STREAMLINED)

2212

Hyperphosphataemia associated with chronic renal failure

9296G **Clopidogrel with aspirin**, Tablet 75 mg (as hydrogen sulfate)-100 mg (*CoPlavix, DuoCover*)

Authority required (STREAMLINED)

3218

Treatment of acute coronary syndromes (myocardial infarction or unstable angina) to prevent early and long-term atherothrombotic events

Authority required (STREAMLINED)

3219

Treatment following cardiac stent insertion

Authority required (STREAMLINED)

1722

Prevention of recurrence of myocardial infarction or unstable angina in patients with a history of symptomatic cardiac ischaemic events while on therapy with low-dose aspirin

NOTE:

Not for prophylaxis of DVT or peripheral arterial disease.

9486G **Glucose indicator—blood**, Reagent strips, 50 (*Lifeline Attest*)

Restricted benefit

For use in patients who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

Lenalidomide

NOTE:

Any queries concerning the arrangements to prescribe lenalidomide 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 Lenalidomide 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). These patients must demonstrate they met initial criteria prior to commencing treatment on the compassionate program and also demonstrate they do not have progressive disease. Baseline and current pathology reports must be submitted with the initial application.

Applications for authority to prescribe lenalidomide should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

NOTE:

Patients receiving lenalidomide via the PBS must be registered in the RevAccess program.

NOTE:

Special Pricing Arrangements apply.

9643M **Lenalidomide**, Capsule 10 mg (*Revlimid*)
9644N **Lenalidomide**, Capsule 15 mg (*Revlimid*)
9645P **Lenalidomide**, Capsule 25 mg (*Revlimid*)

9642L **Lenalidomide**, Capsule 5 mg (*Revlimid*)

Public and private hospital authority required

Initial PBS-subsidised treatment, as monotherapy or in combination with dexamethasone, of a patient with a histological diagnosis of multiple myeloma who has progressive disease after at least 1 prior therapy and who has undergone or is ineligible for a primary stem cell transplant. The patient must have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease.

If the dosing requirement for thalidomide cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein and less than 200 mg per 24 hour Bence-Jones proteinuria.

Thalidomide treatment failure is defined as:
(1) confirmed disease progression during thalidomide treatment or within 6 months of discontinuing thalidomide treatment; or
(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment.

Severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living.

Toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity.

Failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:
(1) less than a 25% reduction in serum or urine M protein; or

(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels.

Lenalidomide will only be subsidised for patients with multiple myeloma who are not receiving concomitant PBS-subsidised bortezomib.

The authority application must be made in writing and must include:
(1) a completed authority prescription form; and
(2) a completed Multiple Myeloma Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response.

To enable confirmation by Medicare Australia, current diagnostic reports of at least one of the following are required:
(a) the level of serum monoclonal protein; or
(b) Bence-Jones proteinuria — the results of 24-hour urinary light chain M protein excretion; or
(c) the serum level of free kappa and lambda light chains; or
(d) bone marrow aspirate or trephine; or
(e) if present, the size and location of lytic bone lesions (not including compression fractures); or
(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (either previous or current serum M protein less than 10 g per L and urinary Bence-Jones protein undetectable or less than 200 mg per 24 hours) must be provided; and
(3) duration of thalidomide and daily dose prescribed; and
(4) a signed patient acknowledgment

Public and private hospital authority required

Continuing PBS-subsidised treatment, as monotherapy or in combination with dexamethasone, of multiple myeloma in a patient who has previously been issued with an authority prescription for lenalidomide and who does not have progressive disease.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Authority applications for continuing treatment may be made by telephone to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)

8628D **Montelukast sodium**, Chewable tablet 5 mg (base) (*Singulair*)

Authority required (STREAMLINED)

2618

First-line preventer medication, as the single preventer agent for children aged 6 to 14 years with frequent intermittent or mild persistent asthma, as an alternative to sodium cromoglycate or nedocromil sodium

Authority required (STREAMLINED)

3217

Prevention of exercise-induced asthma, as an alternative to adding salmeterol xinafoate or eformoterol fumarate, in a child aged 6 to 14 years whose asthma is otherwise well controlled while receiving optimal dose inhaled corticosteroid, but who requires short-acting beta-2 agonist 3 or more times per week for prevention or relief of residual exercise-related symptoms

9294E **Olanzapine**, Powder for injection 210 mg (as pamoate monohydrate) with diluent (*Zyprexa Relprevv*)
9295F **Olanzapine**, Powder for injection 300 mg (as pamoate monohydrate) with diluent (*Zyprexa Relprevv*)

Authority required (STREAMLINED)

1589

Schizophrenia

CAUTION:

Monitor for post-injection syndrome for at least three hours after each injection.

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

NOTE:

Special Pricing Arrangements apply.

9491M **Polyethylene glycol 400**, Eye drops 2.5 mg per mL (0.25%), 15 mL (*Blink Intensive Tears*)
5559N **Polyethylene glycol 400**, Eye drops 2.5 mg per mL (0.25%), 15 mL (*Blink Intensive Tears*)

Restricted benefit

Severe dry eye syndrome, including Sjogren's syndrome

NOTE:

The in-use shelf life of Blink Intensive Tears multi-dose formulation is 45 days from the date of opening.

9492N **Polyethylene glycol 400**, Eye drops 2.5 mg per mL (0.25%), 15 mL (*Blink Intensive Tears*)

Restricted benefit

For use in patients who have severe dry eye syndrome, including Sjogren's syndrome, and who are receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the Plan or coordination of the Arrangements

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

NOTE:

The in-use shelf life of Blink Intensive Tears multi-dose formulation is 45 days from the date of opening.

9493P **Polyethylene glycol 400**, Eye drops 2.5 mg per mL (0.25%), single dose units 0.4 mL, 20 (*Blink Intensive Tears*)

Authority required (STREAMLINED)

1359

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops.

5560P **Polyethylene glycol 400**, Eye drops 2.5 mg per mL (0.25%), single dose units 0.4 mL, 20 (*Blink Intensive Tears*)

Authority required

Severe dry eye syndrome in patients who are sensitive to preservatives in multi-dose eye drops

9151P **Pramipexole hydrochloride**, Tablet 125 micrograms (*Sifrol*)
9153R **Pramipexole hydrochloride**, Tablet 1 mg (*Sifrol*)
9152Q **Pramipexole hydrochloride**, Tablet 250 micrograms (*Sifrol*)

CAUTION:

Episodes of sudden onset of sleep without warning, during activity, have been reported with this drug.

NOTE:

Care should be taken when treating patients with advanced age and significant cognitive impairment with dopamine agonists.

Restricted benefit

Parkinson disease

9496T **Prasugrel**, Tablet 10 mg (as hydrochloride) (*Effient*)
9495R **Prasugrel**, Tablet 5 mg (as hydrochloride) (*Effient*)

Authority required (STREAMLINED)

3208

Treatment of acute coronary syndrome (myocardial infarction or unstable angina) managed by percutaneous coronary intervention in combination with aspirin

9488J **Sunitinib**, Capsule 12.5 mg (as malate) (*Sutent*)
9489K **Sunitinib**, Capsule 25 mg (as malate) (*Sutent*)
9490L **Sunitinib**, Capsule 50 mg (as malate) (*Sutent*)

NOTE:

Any queries concerning the arrangements to prescribe sunitinib malate 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 Sunitinib 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).

Written applications for authority to prescribe sunitinib malate should be forwarded to:

Medicare Australia

Prior Written Approval of Specialised Drugs

Reply Paid 9826

GPO Box 9826

HOBART TAS 7001

Sunitinib malate is not PBS-subsidised for the treatment of patients with resectable malignant gastrointestinal stromal tumours.

Authority required

Initial PBS-subsidised treatment as monotherapy of a patient with WHO performance status of 2 or less with a metastatic or unresectable malignant gastrointestinal stromal tumour after failure of imatinib mesylate treatment due to resistance or intolerance.

Applications for authorisation must be in writing and must include:

(1) a completed authority prescription form; and

(2) a completed Sunitinib Malate (Sutent) PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form [may be downloaded from the Medicare Australia website (www.medicareaustralia.gov.au)]; and

(3) a signed patient acknowledgement.

Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib

Authority required

Continuing PBS-subsidised treatment as monotherapy of a patient with WHO performance status of 2 or less with a metastatic or unresectable malignant gastrointestinal stromal tumour who has previously been issued with an authority prescription for sunitinib and who does not have progressive disease.

Applications for continuing treatment may be made by telephone (1800 700 270, hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients who have failed to respond or who are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.

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

NOTE:

No applications for increased maximum quantities and/or repeats will be authorised.

NOTE:

Special Pricing Arrangements apply.

6358P **Tenofovir disoproxil fumarate**, Tablet 300 mg (*Viread*)

Private hospital authority required

Treatment of HIV infection in patients with CD4 cell counts of less than 500 per cubic millimetre

Private hospital authority required

Treatment of HIV infection in patients with viral load of greater than 10,000 copies per mL

Private hospital authority required

Treatment, as sole PBS-subsidised therapy, of chronic hepatitis B in a patient who is nucleoside analogue naive and satisfies all of the following criteria:

(1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy);

(2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or

(b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection;

(3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

Private hospital authority required

Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria:

(1)(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or

(b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance;

(2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception.

Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy

NOTE:

Patients should have undergone a liver biopsy at some point since initial diagnosis to obtain histological evidence of chronic hepatitis.

Patients may receive tenofovir treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

NOTES

The text of notes mentioned above:

8627C **Montelukast sodium**, Chewable tablet 4 mg (base) (*Singulair*)

NOTE:

Montelukast sodium is not PBS-subsidised for use in a child aged 2 to 5 years with moderate to severe asthma. It is not intended as an alternative for a child aged 2 to 5 years who requires a corticosteroid as a preventer medication.

Montelukast sodium is not subsidised in a child aged 2 to 5 years for use in combination with other preventer medications. PBS subsidy for montelukast sodium will therefore cease for a child aged 2 to 5 years who requires a preventer medication in addition to montelukast sodium.

8628D **Montelukast sodium**, Chewable tablet 5 mg (base) (*Singulair*)

NOTE:

Montelukast sodium is not PBS-subsidised for use in a patient aged 15 years or older, or for use in addition to a long-acting beta-agonist in any age group, or for use as a single second line preventer, as an alternative to corticosteroids, in a child aged 6 to 14 years with moderate to severe asthma.

Ambrisentan

Bosentan monohydrate

Epoprostenol sodium

Iloprost trometamol

Sildenafil citrate

Sitaxentan sodium

NOTE:

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

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

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

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

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

(b) iloprost trometamol, of:

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

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

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

(c) epoprostenol sodium, of:

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

— primary pulmonary hypertension, in patients with disease of WHO Functional Class IV severity; AND

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

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

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

From 1 December 2009, adult patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary.

(New baselines may be submitted where the patient has failed to respond to their current treatment.)

The following provides some explanatory notes regarding the availability of PBS-subsidised treatment of patients under the age of 18 years with:

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

(b) iloprost trometamol, of:

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

— primary pulmonary hypertension, in patients with disease of WHO Functional Class IV severity; AND

(c) epoprostenol sodium, of:

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

— primary pulmonary hypertension, in patients with disease of WHO Functional Class IV severity; AND

(d) sildenafil citrate, of primary pulmonary hypertension in patients with disease of WHO Functional Class III severity;

AND

(e) sitaxentan sodium, of primary pulmonary hypertension in patients with disease of WHO Functional Class III severity; AND

(f) ambrisentan, of primary pulmonary hypertension in patients with disease of WHO Functional Class III or IV severity.

From 1 December 2009, patients under the age of 18 years can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment with 1 of these 6 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted. It also means that no new baseline measurements will be necessary. (New baselines may be submitted where the patient has failed to respond to their current treatment.)

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

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

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

(ii) mPAP greater than 30 mmHg with exercise and PCWP less than 18 mmHg; or

(iii) where a right heart catheter cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

2. Definition of WHO Functional Class III or IV disease severity.

(a) WHO Functional Class III disease severity is defined as follows:

Patients with pulmonary hypertension resulting in marked limitation of physical activity who are comfortable at rest and on ordinary physical activity experience dyspnoea or fatigue, chest pain or near syncope.

(b) WHO Functional Class IV disease severity is defined as follows:

Patients with the inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnoea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

3. Designated hospitals.

Refer to the Medicare Australia website at www.medicareaustralia.gov.au for a list of designated hospitals.

NOTE:

4. Test requirements to establish baseline for initiation of treatment and response to treatment for continuation of treatment.

(a) Initiation of treatment.

The first written application for PBS-subsidised treatment with the first PAH agent should be accompanied by the results of a right heart catheter (RHC) composite assessment, plus an echocardiograph

(ECHO) composite assessment, plus a 6 minute walk test (6MWT) to establish the patient's baseline measurements.

Where it is not possible to perform all 3 tests above on clinical grounds, the following list outlines the preferred test combination, in descending order, for the purposes of initiation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstances where a RHC cannot be performed on clinical grounds, applications may be submitted to Medicare Australia for consideration based on the results of the following test combinations, which are listed in descending order of preference:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test/s could not be conducted must be provided with the authority application.

(b) Continuation of treatment.

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be provided with each written continuing treatment application (i.e. every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted.

In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be provided with the application.

The test(s) results provided with the application for continuing treatment must be no more than 2 months old at the time of application.

5. Definition of response to a PAH agent or prior vasodilator treatment.

For adult patients with 2 or more baseline tests, response to treatment is defined as 2 or more tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For adult patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

For patients aged less than 18 years, response to treatment is defined as at least 1 of the baseline tests demonstrating stability or improvement of disease, as assessed by a physician from a designated hospital.

6. Authority approval requirements.

(a) Initiation of PBS-subsidised treatment with a PAH agent, where the patient has not received prior PBS-subsidised treatment with that agent.

All applications for initial treatment must be made in writing, must include a completed authority prescription and must be submitted to Medicare Australia for authorisation. The total duration of initial PBS-subsidised treatment that will be approved with this first written application is up to 6 months, based on the dosage recommendations in the TGA-approved Product Information.

Bosentan only:

Approvals for the first authority prescription will be limited to 1 month of therapy with the 62.5 mg strength tablet, with the quantity approved based on the dosage recommendations in the Therapeutic Goods Administration (TGA)-approved Product Information. No repeats will be authorised for this prescription. The second authority prescription may be written for either the 62.5 mg tablet or the 125 mg tablet strengths. Where the 62.5 mg tablet strength is required, please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) for further advice. Approvals for the second authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats. The approved second authority prescription will be returned to the prescriber by Medicare Australia 2 weeks after the date of the approval of the first authority prescription, to allow for the uninterrupted completion of the 6 month initial treatment course. Medicare Australia will contact prescribers prior to dispatch of the second authority prescription to confirm the tablet strength required for the patient.

Patients who received non-PBS-subsidised treatment with ambrisentan prior to 1 December 2009:

For patients with primary pulmonary hypertension or pulmonary arterial hypertension secondary to connective tissue disease who were commenced on treatment with ambrisentan prior to 1 December 2009 and who have received less than 6 months treatment with ambrisentan at the time of application, the first application for PBS-subsidised treatment must include, where available, all 3 test results at the time that the patient commenced treatment with ambrisentan, bosentan monohydrate, iloprost trometamol, epoprostenol sodium, sildenafil citrate or sitaxentan sodium, whichever was initiated first.

(b) Continuation of treatment.

Written applications for continuing treatment for patients who have demonstrated an adequate response to their current treatment must be submitted to Medicare Australia for authorisation every 6 months. Approvals will be limited to provide sufficient supply for up to a maximum of 6 months of treatment, based on the dosage recommendations in the TGA-approved Product Information.

The assessment of the patient's response to the first and subsequent 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

Applications for continuing treatment with a PAH agent should be made prior to the completion of the 6 month treatment course to ensure continuity for those patients who respond to treatment, as assessed by the treating physician.

(c) Swapping between PAH agents.

For eligible patients, applications to swap between these 6 drugs must be made under the relevant initial treatment restriction. Patients should be assessed for response to the treatment they are ceasing at the time the application to swap therapy is being made. Patients who fail to demonstrate a response or for whom no assessment results are submitted with the application to swap therapy may not re-commence PBS-subsidised treatment with the drug they are ceasing.

It is important that patients are assessed for response to every course of treatment approved within the timeframes specified in the relevant restriction, in order to maximise the choice of treatment.

To avoid confusion, applications for patients who wish to swap to an alternate treatment should be accompanied by the previously approved authority prescription, or remaining repeats, for the treatment the patient is ceasing.

(d) Cessation of treatment — bosentan patients only.

Patients who fail to demonstrate a response to PBS-subsidised bosentan monohydrate treatment at the time where an assessment is required must cease PBS-subsidised bosentan monohydrate therapy.

For patients ceasing treatment, approval will only be granted to provide sufficient supply of the 62.5 mg tablet strength to allow gradual dose reduction over a period of no more than 1 month duration. Prescribers should telephone Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday) to receive authorisation for this final supply and to ensure no unintended break in treatment occurs.

7. Re-treatment with a PAH agent.

Patients who do not respond to treatment are not eligible to receive further PBS-subsidised treatment with that agent under any circumstances.

8. Further information.

A tabulated representation of the above information and the restriction can be obtained from the Medicare Australia website at www.medicareaustralia.gov.au.

REPATRIATION PHARMACEUTICAL BENEFITS

The change to the Repatriation Pharmaceutical Benefits Schedule is effective from 1 December 2009. The Schedule is updated on the first day of each month and is available on the Internet at www.pbs.gov.au.

SUMMARY OF CHANGES

ALTERATION

Alteration — Item Description

From:
4179Y **Clopidogrel hydrogen sulfate**, Tablet 75 mg (base) (*Iscover, Plavix*)
To:
4179Y **Clopidogrel**, Tablet 75 mg (as hydrogen sulfate) (*Iscover, Plavix*)