



**Australian Government**

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**Department of Health**

**SCHEDULE OF PHARMACEUTICAL  
BENEFITS**

**SUMMARY OF CHANGES**

**EFFECTIVE 1 November 2013**

## PHARMACEUTICAL BENEFITS

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 November 2013. The Schedule is updated on the first day of each month and is available on the Internet at [www.pbs.gov.au](http://www.pbs.gov.au).

### Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply as at 1 November 2013 and are included, where applicable, in prices published in the Schedule —

Dispensing Fees:	Ready-prepared	\$6.63
	Dangerous drug fee	\$2.71
	Extemporaneously-prepared	\$8.67
	Allowable additional patient charge*	\$4.11
Additional Fees (for safety net prices):	Ready-prepared	\$1.13
	Extemporaneously-prepared	\$1.48
Patient Co-payments:	General	\$36.10
	Concessional	\$5.90
Safety Net Thresholds:	General	\$1390.60
	Concessional	\$354.00
Safety Net Card Issue Fee:		\$9.06

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

## SUMMARY OF CHANGES

### Additions

#### Addition – Item

- 2806Q **Amino Acid Formula With Vitamins And Minerals Without Phenylalanine**, amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g jars (*PKU Lophlex Sensation 20*)
- 2805P **Iron Polymaltose**, iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules (*Ferrosig, Ferrum H*)

#### Addition – Brand

- 8200N *Azithromycin-GA, UA* – **Azithromycin**, azithromycin 500 mg tablet, 2
- 8336R *Azithromycin-GA, UA* – **Azithromycin**, azithromycin 500 mg tablet, 2
- 8295N *Pharmacor Candesartan 4, CR* – **Candesartan**, candesartan cilexetil 4 mg tablet, 30
- 8296P *Pharmacor Candesartan 8, CR* – **Candesartan**, candesartan cilexetil 8 mg tablet, 30
- 8297Q *Pharmacor Candesartan 16, CR* – **Candesartan**, candesartan cilexetil 16 mg tablet, 30
- 8889W *Pharmacor Candesartan 32, CR* – **Candesartan**, candesartan cilexetil 32 mg tablet, 30
- 9106G *Doxycycline Sandoz, HX* – **Doxycycline**, doxycycline 50 mg tablet, 25
- 8002E *Famciclovir SCP 250, CR* – **Famciclovir**, famciclovir 250 mg tablet, 21
- 8217L *Famciclovir SCP 250, CR* – **Famciclovir**, famciclovir 250 mg tablet, 56
- 2546B *Aldiq, QA* – **Imiquimod**, imiquimod 5% (12.5 mg/250 mg) cream, 12 x 250 mg sachets
- 8627C *T Lukast, AF* – **Montelukast**, montelukast 4 mg tablet: chewable, 28
- 8628D *T Lukast, AF* – **Montelukast**, montelukast 5 mg tablet: chewable, 28
- 8508T *Rabeprazole Actavis 20, UA* – **Rabeprazole**, rabeprazole sodium 20 mg tablet: enteric, 30 tablets
- 8509W *Rabeprazole Actavis 20, UA* – **Rabeprazole**, rabeprazole sodium 20 mg tablet: enteric, 30 tablets

### Deletions

#### Deletion – Item

- 2103Q **Tiaprofenic Acid**, tiaprofenic acid 300 mg tablet, 60 (*Surgam*)

#### Deletion – Brand

- 1891M *Amoxycillin/ Clavulanic Acid 500/125 generichealth, GQ* – **Amoxycillin + Clavulanic Acid**, amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10
- 5008N *Amoxycillin/ Clavulanic Acid 500/125 generichealth, GQ* – **Amoxycillin + Clavulanic Acid**, amoxycillin 500 mg + clavulanic acid 125 mg tablet, 10 (**Dental**)
- 8331L *Omeprazole Winthrop, WA* – **Omeprazole**, omeprazole 20 mg tablet: enteric, 30 tablets
- 8333N *Omeprazole Winthrop, WA* – **Omeprazole**, omeprazole 20 mg tablet: enteric, 30 tablets
- 3050M *Perindopril generichealth, GQ* – **Perindopril**, perindopril erbumine 2 mg tablet, 30
- 1968N *Quinapril generichealth, GQ* – **Quinapril**, quinapril 5 mg tablet, 30
- 9120B *Ramipril generichealth, GQ* – **Ramipril**, ramipril 1.25 mg capsule, 30
- 2791X *Trandolapril generichealth, GQ* – **Trandolapril**, trandolapril 500 microgram capsule, 28
- 2792Y *Trandolapril generichealth, GQ* – **Trandolapril**, trandolapril 1 mg capsule, 28
- 2793B *Trandolapril generichealth, GQ* – **Trandolapril**, trandolapril 2 mg capsule, 28
- 8758Y *Trandolapril generichealth, GQ* – **Trandolapril**, trandolapril 4 mg capsule, 28

### Alterations

#### Alteration – Brand Name

From:

- 9446E *KetoCal, SB* – **High Fat Formula With Vitamins, Minerals And Trace Elements And Low In Protein And Carbohydrate**, high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral liquid: powder for, 300 g

To:

- 9446E *KetoCal 4:1, SB* – **High Fat Formula With Vitamins, Minerals And Trace Elements And Low In Protein And Carbohydrate**, high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral liquid: powder for, 300 g

From:

- 1324Q *Metohexal, SZ* – **Metoprolol Tartrate**, METOPROLOL TARTRATE Tablet 50 mg, 100

To:

- 1324Q *Metoprolol Sandoz, SZ* – **Metoprolol Tartrate**, METOPROLOL TARTRATE Tablet 50 mg, 100

From:

- 1325R *Metohexal, SZ* – **Metoprolol Tartrate**, METOPROLOL TARTRATE Tablet 100 mg, 60

To:

1325R *Metoprolol Sandoz, SZ – Metoprolol Tartrate*, METOPROLOL TARTRATE Tablet 100 mg, 60

### Alteration – Number of Repeats

		From	To
8807M	<b>Iron Sucrose</b> , iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL vials ( <i>Venofer</i> )	0	5

### Alteration – Restriction

8807M **Iron Sucrose**, iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL vials (*Venofer*)

### Alteration – Restriction and Note

The note relating to treatment supervised by a dietician, together with a metabolic physician and/or neurologist is now part of the restriction, resulting in the note being deleted.

9446E **High Fat Formula With Vitamins, Minerals And Trace Elements And Low In Protein And Carbohydrate**, high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral liquid: powder for, 300 g (*KetoCal 4:1*)

### Alteration – Caution

9294E **Olanzapine**, olanzapine 210 mg injection: modified release [1 x 210 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack (*Zyprexa Relprevv*)

9295F **Olanzapine**, olanzapine 300 mg injection: modified release [1 x 300 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack (*Zyprexa Relprevv*)

9303P **Olanzapine**, olanzapine 405 mg injection: modified release [1 x 405 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack (*Zyprexa Relprevv*)

### Alteration – Authority required (STREAMLINED) Code

Please note the restriction for these items has not changed.

9294E **Olanzapine**, olanzapine 210 mg injection: modified release [1 x 210 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack (*Zyprexa Relprevv*)

9295F **Olanzapine**, olanzapine 300 mg injection: modified release [1 x 300 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack (*Zyprexa Relprevv*)

9303P **Olanzapine**, olanzapine 405 mg injection: modified release [1 x 405 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack (*Zyprexa Relprevv*)

### Alteration – Manufacturer's Code

		From	To
8282X	<i>S-26 LF, AS – Milk Powder Lactose Free Formula</i> , milk powder lactose free formula oral liquid: powder for, 900 g	PF	AS
8283Y	<i>S-26 LF, AS – Milk Powder Lactose Free Formula</i> , milk powder lactose free formula oral liquid: powder for, 900 g	PF	AS

## Advance Notices

### Advance Notices – Deletion of Item

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

8373Q **Leflunomide**, leflunomide 100 mg tablet [3 tablets] (&) leflunomide 20 mg tablet [30 tablets], 33 (*Arava*)

8629E **Triglycerides Medium Chain Formula**, triglycerides medium chain formula oral liquid: powder for, 420 g (*Caprilon*)

### Advance Notices – Deletion of Brand

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

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

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

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

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

## SECTION 100 – HIGHLY SPECIALISED DRUGS PROGRAM

### Alterations

#### Alteration – Restriction

6120D	<b>Dornase Alfa</b> , dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules ( <i>Pulmozyme</i> )( <b>Private</b> )
5704F	<b>Dornase Alfa</b> , dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules ( <i>Pulmozyme</i> )( <b>Public</b> )
2008Q	<b>Mannitol</b> , MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1 ( <i>bronchitol</i> )( <b>Private</b> )
2015C	<b>Mannitol</b> , MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1 ( <i>bronchitol</i> )( <b>Public</b> )

## REPATRIATION PHARMACEUTICAL BENEFITS

### Deletions

#### Deletion – Item

4320J	<b>Pregabalin</b> , pregabalin 25 mg capsule, 56 ( <i>Lyrica</i> )
4322L	<b>Pregabalin</b> , pregabalin 75 mg capsule, 56 ( <i>Lyrica</i> )
4323M	<b>Pregabalin</b> , pregabalin 150 mg capsule, 56 ( <i>Lyrica</i> )
4324N	<b>Pregabalin</b> , pregabalin 300 mg capsule, 56 ( <i>Lyrica</i> )

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max. Qty \$	Maximum Recordable Value for Safety Net \$	Brand Name and Manufacturer	
<b>AMINO ACID FORMULA WITH VITAMINS AND MINERALS WITHOUT PHENYLALANINE</b>								
<b><u>Restricted benefit</u></b>								
Phenylketonuria								
2806Q NP	amino acid formula with vitamins and minerals without phenylalanine oral semi-solid, 36 x 109 g jars	3	5	..	*1852.95	36.10	PKU Lophlex Sensation 20	SB
<b>HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE</b>								
<b><u>Restricted benefit</u></b>								
Ketogenic diet								
<b>The Clinical criteria is:</b>								
Patient must have intractable seizures requiring treatment with a ketogenic diet; OR								
Patient must have a glucose transport protein defect; OR								
Patient must have pyruvate dehydrogenase deficiency.								
KetoCal 4:1 should only be used under strict supervision of a dietician, together with a metabolic physician and/or neurologist.								
<b><u>Note</u></b>								
Authorities for increased maximum quantities, up to a maximum of 48, may be authorised.								
9446E NP	high fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate oral liquid: powder for, 300 g	24	5	..	*1037.67	36.10	KetoCal 4:1	SB
<b>IRON POLYMALTOSE</b>								
<b><u>Authority required (STREAMLINED)</u></b>								
<b>4302</b>								
Iron deficiency anaemia								
<b>The Treatment criteria is:</b>								
Patient must be undergoing chronic haemodialysis.								
2805P NP	iron (as polymaltose) 100 mg/2 mL injection, 5 x 2 mL ampoules	1	5	..	38.78	36.10	<sup>a</sup> Ferrosig <sup>a</sup> Ferrum H	SI AS
<b>IRON SUCROSE</b>								
<b><u>Authority required (STREAMLINED)</u></b>								
<b>4292</b>								
Iron deficiency anaemia								
<b>The Treatment criteria is:</b>								
Patient must be undergoing chronic haemodialysis,								
<b>AND the Clinical criteria is:</b>								
The treatment must be in combination with an erythropoiesis stimulating agent,								
<b>AND the Clinical criteria is:</b>								
Patient must have had a documented hypersensitivity reaction to iron polymaltose,								
<b>AND the Clinical criteria is:</b>								
Patient must be a person in whom continued intravenous iron therapy is appropriate.								
8807M NP	iron (as sucrose) 100 mg/5 mL injection, 5 x 5 mL vials	1	5	..	139.69	36.10	Venofer	AS
<b>OLANZAPINE</b>								
<b><u>Authority required (STREAMLINED)</u></b>								
<b>4304</b>								
Schizophrenia								
<b><u>Caution</u></b>								
Monitor for post-injection syndrome for at least two hours after each injection.								
<b><u>Note</u></b>								
Special Pricing Arrangements apply.								
<b><u>Note</u></b>								
<b>Shared Care Model:</b>								
For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised								

## GENERAL PHARMACEUTICAL BENEFITS

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for	Maximum Recordable Value for	Brand Name and Manufacturer	
					Max. Qty \$	Safety Net \$		
arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.								
9294E NP	olanzapine 210 mg injection: modified release [1 x 210 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack	2	5	..	*499.99	36.10	Zyprexa Relprevv	LY
9295F NP	olanzapine 300 mg injection: modified release [1 x 300 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack	2	5	..	*809.47	36.10	Zyprexa Relprevv	LY
9303P NP	olanzapine 405 mg injection: modified release [1 x 405 mg vial] (&) inert substance diluent [1 x 3 mL vial], 1 pack	1	5	..	499.99	36.10	Zyprexa Relprevv	LY

## HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

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

### **DORNASE ALFA**

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

**4288**

Cystic fibrosis

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

Patient must have a forced vital capacity (FVC) greater than 40% predicted for age, gender and weight,

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

Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease),

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

Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to dornase alfa therapy, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with dornase alfa following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
- (2) the patient or the patient's family (in the case of paediatric patients) must report improvement in the patient's airway clearance; AND
- (3) the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy, then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)

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

**4300**

Cystic fibrosis

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

Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR

Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR

Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR

Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy,

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

Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

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

**4296**

Cystic fibrosis

**MANNITOL**

**Authority required (STREAMLINED)**

4299

## Cystic fibrosis

**The Clinical criteria is:**

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information mannitol initiation dose assessment, prior to mannitol therapy. If the patient has a negative hyperresponsiveness test they may be eligible for PBS subsidised treatment with mannitol.

**AND the Clinical criteria is:**

Patient must have a forced expiratory volume in 1 second (FEV1) greater than 30% predicted for age, gender and height.

**AND the Clinical criteria is:**

Patient must be intolerant or inadequately responsive to dornase alfa,

**AND the Clinical criteria is:**

Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease).

**AND the Population criteria is:**

Patient must be 6 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of mannitol therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to mannitol therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient's family (in the

## HIGHLY SPECIALISED DRUGS PROGRAM (Public Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty \$		
	case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.						
	To be eligible for continued PBS-subsidised treatment with mannitol following 3 months of initial treatment:						
	(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND						
	(2) the patient or the patient's family (in the case of paediatric patients) must report improvement in the patient's airway clearance; AND						
	(3) the treating physician(s) must report a benefit in the clinical status of the patient.						
	Further reassessments involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that mannitol treatment is continuing to produce worthwhile benefits. Mannitol therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.						
	Other aspects of treatment, such as physiotherapy, must be continued.						
	Where there is documented evidence that a patient already receiving mannitol therapy would have met the criteria for subsidy then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)						
	<b><u>Authority required (STREAMLINED)</u></b>						
	<b>4293</b>						
	Cystic fibrosis						
	<b>The Clinical criteria is:</b>						
	Patient must have initiated treatment with mannitol prior to 1 August 2012,						
	<b>AND the Clinical criteria is:</b>						
	Patient must have undergone a comprehensive assessment involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis team, which documents agreement that mannitol treatment is continuing to produce a worthwhile benefit,						
	<b>AND the Population criteria is:</b>						
	Patient must be 6 years of age or older.						
	Further reassessments are to be undertaken and documented every 6 months. Treatment with mannitol should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.						
	<b><u>Note</u></b>						
	Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.						
	<b><u>Note</u></b>						
	It is highly desirable that all patients be included in the national cystic fibrosis patient database.						
2015C	MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1	4	5	..	*1736.00	bronchitol	XA

## HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

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

### **DORNASE ALFA**

#### **Authority required**

Cystic fibrosis

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

Patient must have a forced vital capacity (FVC) greater than 40% predicted for age, gender and weight,

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

Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease),

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

Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation.

Prior to dornase alfa therapy, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy.

To be eligible for continued PBS-subsidised treatment with dornase alfa following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
- (2) the patient or the patient's family (in the case of paediatric patients) must report improvement in the patient's airway clearance; AND
- (3) the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that dornase alfa treatment is continuing to produce worthwhile benefits. Dornase alfa therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Other aspects of treatment, such as physiotherapy, must be continued.

Where there is documented evidence that a patient already receiving dornase alfa therapy would have met the criteria for subsidy, then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)

#### **Authority required**

Cystic fibrosis

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

Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR

Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR

Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR

Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy,

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

Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of dornase alfa therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented involving the patient, the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team to establish agreement that dornase alfa treatment is continuing to produce worthwhile benefit. Treatment with dornase alfa should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

#### **Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

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

## HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed	Brand Name and Manufacturer
					Price for Max. Qty \$	
	Patient must have initiated treatment with dornase alfa at an age of less than 5 years, <b>AND the Clinical criteria is:</b> Patient must have undergone a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit, <b>AND the Population criteria is:</b> Patient must be 5 years of age or older. Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use. <b><u>Authority required</u></b> Cystic fibrosis <b>The Clinical criteria is:</b> Patient must have initiated treatment with dornase alfa prior to 1 November 2009, <b>AND the Clinical criteria is:</b> Patient must have undergone a comprehensive assessment, involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis treatment team which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit, <b>AND the Population criteria is:</b> Patient must be less than 5 years of age. Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with dornase alfa should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use. <b><u>Note</u></b> Dornase alfa is not PBS-subsidised for use in combination with PBS-subsidised mannitol. <b><u>Note</u></b> It is highly desirable that all patients be included in the national cystic fibrosis patient database.					
6120D	dornase alfa 2.5 mg/2.5 mL inhalation: solution, 30 x 2.5 mL ampoules	2	5	..	*2406.63	Pulmozyme RO
	<b>MANNITOL</b> <b><u>Authority required</u></b> Cystic fibrosis <b>The Clinical criteria is:</b> Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information mannitol initiation dose assessment, prior to mannitol therapy. If the patient has a negative hyperresponsiveness test they may be eligible for PBS subsidised treatment with mannitol, <b>AND the Clinical criteria is:</b> Patient must have a forced expiratory volume in 1 second (FEV1) greater than 30% predicted for age, gender and height, <b>AND the Clinical criteria is:</b> Patient must be intolerant or inadequately responsive to dornase alfa, <b>AND the Clinical criteria is:</b> Patient must have evidence of chronic suppurative lung disease (cough and sputum most days of the week, or greater than 3 respiratory tract infections of more than 2 weeks' duration in any 12 months, or objective evidence of obstructive airways disease), <b>AND the Population criteria is:</b> Patient must be 6 years of age or older. Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. The prescribing of mannitol therapy under the HSD program is limited to such physicians. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be by a specialist physician or paediatrician in consultation with such a unit. The measurement of lung function is to be conducted by independent (other than the treating doctor) experienced personnel at an established lung function testing laboratory, unless this is not possible because of geographical isolation. Prior to mannitol therapy, a baseline measurement of FEV1 must be undertaken during a stable period of the disease. Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily. FEV1 measurement (single test under conditions as above) and a global assessment of the patient involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented following 3 months of initial therapy. To be eligible for continued PBS-subsidised treatment with mannitol following 3 months of initial treatment: (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND					

## HIGHLY SPECIALISED DRUGS PROGRAM (Private Hospital)

Code	Name, Restriction, Manner of Administration and Form	Max. Qty (Packs)	No. of Rpts	Premium \$	Dispensed Price for Max.		Brand Name and Manufacturer
					Qty	\$	
	(2) the patient or the patient's family (in the case of paediatric patients) must report improvement in the patient's airway clearance; AND						
	(3) the treating physician(s) must report a benefit in the clinical status of the patient.						
	Further reassessments involving the patient, the patient's family (in the case of paediatric patients), the treating physician(s) and an additional independent member of the cystic fibrosis treatment team must be undertaken and documented at six-monthly intervals to establish that all agree that mannitol treatment is continuing to produce worthwhile benefits. Mannitol therapy should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.						
	Other aspects of treatment, such as physiotherapy, must be continued.						
	Where there is documented evidence that a patient already receiving mannitol therapy would have met the criteria for subsidy then the patient is eligible to continue treatment under the HSD program. Where such evidence is not available, patients will need to satisfy the initiation and continuation criteria as for new patients. (Four weeks is considered a suitable wash-out period.)						
	<b><u>Authority required</u></b>						
	Cystic fibrosis						
	<b>The Clinical criteria is:</b>						
	Patient must have initiated treatment with mannitol prior to 1 August 2012,						
	<b>AND the Clinical criteria is:</b>						
	Patient must have undergone a comprehensive assessment involving the patient's family, the treating physician and an additional independent member of the cystic fibrosis team, which documents agreement that mannitol treatment is continuing to produce a worthwhile benefit,						
	<b>AND the Population criteria is:</b>						
	Patient must be 6 years of age or older.						
	Further reassessments are to be undertaken and documented every 6 months. Treatment with mannitol should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.						
	<b><u>Note</u></b>						
	Mannitol is not PBS-subsidised for use in combination with PBS-subsidised dornase alfa.						
	<b><u>Note</u></b>						
	It is highly desirable that all patients be included in the national cystic fibrosis patient database.						
2008Q	MANNITOL Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers, 1	4	5	..	*1782.63	bronchitol	XA