PB 69 of 2013

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2013 (No. 12)

National Health Act 1953

I, FELICITY McNEILL, First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health, delegate of the Minister for Health, make this Instrument under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 3rd October 2013

FELICITY McNEILL
First Assistant Secretary
Pharmaceutical Benefits Division
Department of Health

1 Name of Instrument

(1) This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2013 (No. 12)*.

(2) This Instrument may also be cited as PB 69 of 2013.

2 Commencement

This Instrument commences on 1 November 2013.

3 Amendment of *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012)

Schedule 1 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012).

Schedule 1 Amendments

[1] Schedule 1, entry for Amino acid formula with vitamins and minerals without phenylalanine

omit from the column headed "Circumstances" (all instances): **C1286** *substitute:* **C4295**

[2] Schedule 1, after entry for Amino acid formula with vitamins and minerals without phenylalanine in the form Oral liquid 174 mL, 30 (PKU Cooler 20)

insert in the columns in the order indicated:

	Oral semi-solid 109 g, 36 (PKU Lophlex Sensation 20)	Oral	PKU Lophlex Sensation 20	SB	MP NP	C4295		3	5	1

[3] Schedule 1, entry for Amoxycillin with Clavulanic Acid in the form Tablet containing 500 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)

(a) *omit:*

			Amoxycillin/ Clavulanic Acid 500/125 generichealth	GQ	PDP	C1836 C1837		10	0	10

(b) *omit:*

			Amoxycillin/ Clavulanic Acid 500/125 generichealth	GQ	MP NP MW	C1836 C1837		10	1	10

[4] Schedule 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) ***[Maximum Quantity 2; Number of Repeats 0]***

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Azithromycin-GA	UA	MP NP	C1405 C1838 C1839	P1838 P1839	2	0	2

[5] Schedule 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate) ***[Maximum Quantity 2; Number of Repeats 2]***

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Azithromycin-GA	UA	MP NP	C1405 C1838 C1839	P1405	2	2	2

[6] Schedule 1, entry for Candesartan in the form Tablet containing candesartan cilexetil 4 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Pharmacor Candesartan 4	CR	MP NP			30	5	30

[7] Schedule 1, entry for Candesartan in the form Tablet containing candesartan cilexetil 8 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Pharmacor Candesartan 8	CR	MP NP				30	5	30	

[8] Schedule 1, entry for Candesartan in the form Tablet containing candesartan cilexetil 16 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Pharmacor Candesartan 16	CR	MP NP				30	5	30	

[9] Schedule 1, entry for Candesartan in the form Tablet containing candesartan cilexetil 32 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Pharmacor Candesartan 32	CR	MP NP				30	5	30	

[10] Schedule 1, entry for Docetaxel in the form Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent

omit:

	Taxotere	SW	MP	C3888 C3892 C3916 C3956 C4078 C4140 C4160 C4239			See Note 3	See Note 3	1	D(100)

[11] Schedule 1, entry for Dornase Alfa

omit all codes from the column headed "Circumstances" and substitute:

4288 C4290 C4291 C4296 C4297 C4298 C4300 C4301

[12] Schedule 1, entry for Doxycycline in the form Tablet 50 mg (as monohydrate)

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Doxycycline Sandoz	HX	MP NP	C1346 C1851 C1852			25	5	25	

[13] Schedule 1, entry for Famciclovir in the form Tablet 250 mg *[Maximum Quantity 21; Number of Repeats 0]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Famciclovir SCP 250	CR	MP NP	C3622 C3623	P3622		21	0	21	

[14] Schedule 1, entry for Famciclovir in the form Tablet 250 mg *[Maximum Quantity 56; Number of Repeats 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Famciclovir SCP 250	CR	MP NP	C3622 C3623	P3623	56	5	56

[15] Schedule 1, entry for High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate in the form Oral powder 300 g (KetoCal)

(a) *omit from the column headed "Form":* **(KetoCal)** *substitute:* **(KetoCal 4:1)**

(b) *omit from the column headed "Brand":* **KetoCal** *substitute:* **KetoCal 4:1**

(c) *omit from the column headed "Circumstances":* **C1578 C1579 C1580** *substitute:* **C4289**

[16] Schedule 1, entry for Imiquimod in the form Cream 50 mg per g, 250 mg single use sachets, 12

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Aldiq	QA	MP	C4229		1	1	1

[17] Schedule 1, entry for Iron Polymaltose Complex

substitute:

Iron Polymaltose Complex	Injection 100 mg (iron) in 2 mL	Injection	Ferrosig	SI	MP NP			5	0	5
					MP NP		P4302	5	5	5
			Ferrum H	AS	MP NP			5	0	5
					MP NP		P4302	5	5	5

[18] Schedule 1, entry for Iron Sucrose

(a) *omit from the column headed "Form":* **ampoule**

(b) *omit from the column headed "Circumstances":* **C2070** *substitute:* **C4292**

(c) *omit from the column headed "Number of Repeats":* **0** *substitute:* **5**

[19] Schedule 1, entry for Mannitol

omit all codes from the column headed "Circumstances" and substitute:

C4293 C4294 C4299 C4303

[20] Schedule 1, entry for Metoprolol in each of the forms: Tablet containing metoprolol tartrate 50 mg; and Tablet containing metoprolol tartrate 100 mg

omit from the column headed "Brand": **Metohexal** *substitute:* **Metoprolol Sandoz**

[21] Schedule 1, entry for Milk powder—lactose free formula in the form Oral powder 900 g (S-26 LF)

omit from the column headed "Responsible Person": **PF** *substitute:* **AS**

[22] Schedule 1, entry for Montelukast in the form Tablet, chewable, 4 mg (as sodium)

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	T Lukast	AF	MP NP	C2617		28	5	28

[23] Schedule 1, entry for Montelukast in the form Tablet, chewable, 5 mg (as sodium)

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	T Lukast	AF	MP NP	C2618 C3217		28	5	28

[24] Schedule 1, entry for Olanzapine in each of the forms: Powder for injection 210 mg (as pamoate monohydrate) with diluent; Powder for injection 300 mg (as pamoate monohydrate) with diluent; and Powder for injection 405 mg (as pamoate monohydrate) with diluent

omit from the column headed "Circumstances": **C1589** *substitute:* **C4304**

[25] Schedule 1, entry for Omeprazole in the form Tablet 20 mg

(a) *omit:*

	Omeprazole Winthrop	WA	MP NP	C4074 C4075 C4089 C4152	P4074	30	1	30

(b) *omit:*

	Omeprazole Winthrop	WA	MP NP	C4074 C4075 C4089 C4152	P4075 P4089 P4152	30	5	30

[26] Schedule 1, entry for Perindopril in the form Tablet containing perindopril erbumine 2 mg

omit:

	Perindopril generichealth	GQ	MP NP			30	5	30

[27] Schedule 1, entry for Quinapril in the form Tablet 5 mg (as hydrochloride)

omit:

	Quinapril generichealth	GQ	MP NP			30	5	30

[28] Schedule 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated) *[Maximum Quantity 30; Number of Repeats 2]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Rabeprazole Actavis 20	UA	MP NP	C1177 C1337 C1533	P1177	30	2	30

[29] Schedule 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated) *[Maximum Quantity 30; Number of Repeats 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Rabeprazole Actavis 20	UA	MP NP	C1177 C1337 C1533	P1337 P1533	30	5	30

[30] Schedule 1, entry for Ramipril in the form Capsule 1.25 mg

omit:

	Ramipril generichealth	GQ	MP NP			30	5	30

[31] Schedule 1, omit entry for Tiaprofenic Acid

[32] Schedule 1, entry for Trandolapril in each of the forms: Capsule 500 micrograms; Capsule 1 mg; Capsule 2 mg; and Capsule 4 mg

omit:

	Trandolapril generichealth	GQ	MP NP			28	5	28

[33] Schedule 4, Part 1, entry for Amino acid formula with vitamins and minerals without phenylalanine

omit from the column headed "Circumstances Code": **C1286** *substitute:* **C4295**

[34] Schedule 4, Part 1, entry for Dornase Alfa

substitute:

Dornase Alfa	C4288			Where the patient is receiving treatment at/from a public hospital Cystic fibrosis Patient must have a forced vital capacity (FVC) greater than 40% predicted for age, gender and weight; 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); 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;	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4288

				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.)	
	C4290			Where the patient is receiving treatment at/from a private hospital Cystic fibrosis Patient must have a forced vital capacity (FVC) greater than 40% predicted for age, gender and weight; 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) 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.)	Compliance with Written or Telephone Authority Required procedures

	C4291			Where the patient is receiving treatment at/from a private hospital Cystic fibrosis Continuing treatment Patient must have initiated treatment with dornase alfa at an age of less than 5 years; 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; 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	Compliance with Written or Telephone Authority Required procedures
	C4296			Where the patient is receiving treatment at/from a public hospital Cystic fibrosis Continuing treatment Patient must have initiated treatment with dornase alfa at an age of less than 5 years; 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; 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	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4296
	C4297			Where the patient is receiving treatment at/from a private hospital Cystic fibrosis Patient must have initiated treatment with dornase alfa prior to 1 November 2009; 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; 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	Compliance with Written or Telephone Authority Required procedures
	C4298			Where the patient is receiving treatment at/from a public hospital Cystic fibrosis Patient must have initiated treatment with dornase alfa prior to 1 November 2009; 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; 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	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4298
	C4300			Where the patient is receiving treatment at/from a public hospital Cystic fibrosis 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;	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4300

				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	
	C4301			Where the patient is receiving treatment at/from a private hospital Cystic fibrosis 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 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	Compliance with Written or Telephone Authority Required procedures

[35] Schedule 4, Part 1, entry for High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate

(a) *omit:*

	C1578			Patients with intractable seizures requiring treatment with a ketogenic diet	
	C1579			Glucose transport protein defects	
	C1580			Pyruvate dehydrogenase deficiency	

(b) *insert in numerical order after existing text:*

	C4289			Ketogenic diet 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	

[36] Schedule 4, Part 1, after entry for Irinotecan

insert:

Iron Polymaltose Complex		P4302		Iron deficiency anaemia Patient must be undergoing chronic haemodialysis	Compliance with Authority Required procedures - Streamlined Authority Code 4302

[37] Schedule 4, Part 1, entry for Iron Sucrose

substitute:

Iron Sucrose	C4292			Iron deficiency anaemia Patient must be undergoing chronic haemodialysis; The treatment must be in combination with an erythropoiesis stimulating agent; Patient must have had a documented hypersensitivity reaction to iron polymaltose; Patient must be a person in whom continued intravenous iron therapy is appropriate	Compliance with Authority Required procedures - Streamlined Authority Code 4292

[38] Schedule 4, Part 1, entry for Mannitol

substitute:

Mannitol	C4293			Where the patient is receiving treatment at/from a public hospital Cystic fibrosis Patient must have initiated treatment with mannitol prior to 1 August 2012; 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; 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	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4293
	C4294			Where the patient is receiving treatment at/from a private hospital Cystic fibrosis Patient must have initiated treatment with mannitol prior to 1 August 2012; 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; 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	Compliance with Written or Telephone Authority Required procedures
	C4299			Where the patient is receiving treatment at/from a public hospital Cystic fibrosis 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; Patient must have a forced expiratory volume in 1 second (FEV1) greater than 30% predicted for age, gender and height; Patient must be intolerant or inadequately responsive to dornase alfa; 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);	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4299

				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 (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.)	
	C4303			Where the patient is receiving treatment at/from a private hospital Cystic fibrosis 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; Patient must have a forced expiratory volume in 1 second (FEV1) greater than 30% predicted for age, gender and height; Patient must be intolerant or inadequately responsive to dornase alfa; 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); 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	Compliance with Written or Telephone Authority Required procedures

				(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.)	

[39] Schedule 4, Part 1, entry for Olanzapine

insert in numerical order after existing text:

	C4304			Schizophrenia	Compliance with Authority Required procedures - Streamlined Authority Code 4304

[40] Schedule 4, Part 1, omit entry for Tiaprofenic Acid