PB 70 of 2013

National Health (Highly specialised drugs program for hospitals) Special Arrangement Amendment Instrument 2013 (No. 7)

National Health Act 1953

I, STEVE DUNLOP, Acting Assistant Secretary, Pharmaceutical Access Branch, Pharmaceutical Benefits Division, Department of Health, delegate of the Minister for Health, make this Amendment Instrument under subsections 100(1) and 100(2) of the *National Health Act 1953.*

Dated 16 October 2013

STEVE DUNLOP
Acting Assistant Secretary
Pharmaceutical Access Branch
Pharmaceutical Benefits Division
Department of Health

---

1 Name of Instrument

(1) This Instrument is the *National Health (Highly specialised drugs program for hospitals) Special Arrangement Amendment Instrument 2013 (No.7)*.

(2) This Instrument may also be cited as PB 70 of 2013.

2 Commencement

This Instrument commences on 1 November 2013.

3 Amendments to PB 116 of 2010

Schedule 1 amends the *National Health (Highly specialised drugs program for hospitals) Special Arrangement 2010* (PB 116 of 2010).

Schedule 1 Amendments

Section 3

[1] Schedule 1 – Entry for Dornase Alfa

Substitute:

Dornase Alfa	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	Inhalation	Pulmozyme	RO	EMP	C4288 C4290 C4291 C4296 C4297 C4298 C4300 C4301	60	5	D

[2] Schedule 1 – Entry for Mannitol

Substitute:

Mannitol	Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers	Inhalation by mouth	Bronchitol	XA	EMP	C4293 C4294 C4299 C4303	4	5	D

[3] Schedule 3 – Entry for Dornase Alfa

Substitute:

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

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

			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.)	
	C4291		Where the patient is receiving treatment at/from a private hospital Continuing treatment Patient must have initiated treatment with dornase alfa at an age of less than 5 years; and 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; and 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 Continuing treatment Patient must have initiated treatment with dornase alfa at an age of less than 5 years; and 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; and 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 Patient must have initiated treatment with dornase alfa prior to 1 November 2009; and 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; and 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 Patient must have initiated treatment with dornase alfa prior to 1 November 2009; and 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; and 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 Patient must be less than 5 years of age. 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 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 – Streamlined Authority Code 4300
	C4301		Where the patient is receiving treatment at/from a private hospital Patient must be less than 5 years of age. 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 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	Compliance with Written or Telephone Authority Required procedures

			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.	

[4] Schedule 3 – Entry for Mannitol

Substitute:

Mannitol	C4293		Where the patient is receiving treatment at/from a public hospital Patient must have initiated treatment with mannitol prior to 1 August 2012; and 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; and 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 Patient must have initiated treatment with mannitol prior to 1 August 2012; and 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; and 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 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 Patient must have a forced expiratory volume in 1 second (FEV1) greater than 30% predicted for age, gender and height and; Patient must be intolerant or inadequately responsive to dornase alfa; and 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 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.)	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4299
	C4303		Where the patient is receiving treatment at/from a private hospital 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	Compliance with Written or Telephone Authority Required procedures

			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; and 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 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.)	