PB 111 of 2015

National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2015 (No. 12)

National Health Act 1953

I, JULIANNE QUAINE, 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 26 November 2015

Julianne Quaine
Assistant Secretary
Pharmaceutical Access Branch
Pharmaceutical Benefits Division
Department of Health

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1 Name of Instrument

(1) This Instrument is the *National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2015 (No. 12).*

(2) This Instrument may also be cited as PB 111 of 2015.

2 Commencement

This Instrument commences on 1 December 2015.

3 Amendment

Amends the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010).

[1] Schedule 1, entry for Dornase alfa in the form Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL and brand Pulmozyme

omit from the column headed 'Circumstances' **: C4288 C4290 C4291 C4296 C4297 C4298 C4300 C4301**

insert: **C5634 C5635 C5715 C5740 C5768 C5800**

[2] Schedule 1, entry for Everolimus in each of the forms Tablet 0.25 mg, Tablet 0.5 mg, Tablet 0.75 mg, Tablet 1 mg

omit from the column headed 'Circumstances' : **C5567 C5599** *insert:* **C5794 C5795**

[3] Schedule 1, entry for Infliximab

substitute:

Infliximab	Powder for I.V. infusion 100 mg	Injection	Inflectra	HH	MP	C3691 C3693 C3819 C3820 C4524 C4535 C4603 C4625 C4626 C4627 C4630 C4705 C4718 C4823 C4836 C4846 C4854 C5077 C5078 C5079 C5084 C5097 C5103 C5109 C5110 C5111 C5112 C5118 C5120 C5149 C5197 C5233 C5234 C5303 C5304 C5311 C5376 C5377 C5440 C5484 C5485 C5570	P3691 P3693 P3819 P3820 P4603 P4625 P4626 P4627 P4630 P4705 P4718 P4823 P4836 P4846 P4854 P5077 P5078 P5079 P5084 P5097 P5103 P5109 P5110 P5111 P5112 P5118 P5120 P5149 P5197 P5233 P5234 P5303 P5304 P5311 P5376 P5377 P5440 P5484 P5485 P5570	1	0	D
			Remicade	JC	MP	C3691 C3693 C3819 C3820 C4524 C4535 C4603 C4625 C4626 C4627 C4630 C4705 C4718 C4823 C4836 C4846 C4854 C5077 C5078 C5079 C5084 C5097 C5103 C5109 C5110 C5111 C5112 C5118 C5120 C5149 C5197 C5233 C5234 C5303 C5304 C5311 C5376 C5377 C5440 C5484 C5485 C5570	P3691 P3693 P3819 P3820 P4603 P4625 P4626 P4627 P4630 P4705 P4718 P4823 P4836 P4846 P4854 P5077 P5078 P5079 P5084 P5097 P5103 P5109 P5110 P5111 P5112 P5118 P5120 P5149 P5197 P5233 P5234 P5303 P5304 P5311 P5376 P5377 P5440 P5484 P5485 P5570	1	0	D

Inflectra	HH	MP	C3691 C3693 C3819 C3820 C4524 C4535 C4603 C4625 C4626 C4627 C4630 C4705 C4718 C4823 C4836 C4846 C4854 C5077 C5078 C5079 C5084 C5097 C5103 C5109 C5110 C5111 C5112 C5118 C5120 C5149 C5197 C5233 C5234 C5303 C5304 C5311 C5376 C5377 C5440 C5484 C5485 C5570	P4535	1	1	D
Remicade	JC	MP	C3691 C3693 C3819 C3820 C4524 C4535 C4603 C4625 C4626 C4627 C4630 C4705 C4718 C4823 C4836 C4846 C4854 C5077 C5078 C5079 C5084 C5097 C5103 C5109 C5110 C5111 C5112 C5118 C5120 C5149 C5197 C5233 C5234 C5303 C5304 C5311 C5376 C5377 C5440 C5484 C5485 C5570	P4535	1	1	D
Inflectra	HH	MP	C3691 C3693 C3819 C3820 C4524 C4535 C4603 C4625 C4626 C4627 C4630 C4705 C4718 C4823 C4836 C4846 C4854 C5077 C5078 C5079	P4524	5	1	D

			C5084 C5097 C5103 C5109 C5110 C5111 C5112 C5118 C5120 C5149 C5197 C5233 C5234 C5303 C5304 C5311 C5376 C5377 C5440 C5484 C5485 C5570				
Remicade	JC	MP	C3691 C3693 C3819 C3820 C4524 C4535 C4603 C4625 C4626 C4627 C4630 C4705 C4718 C4823 C4836 C4846 C4854 C5077 C5078 C5079 C5084 C5097 C5103 C5109 C5110 C5111 C5112 C5118 C5120 C5149 C5197 C5233 C5234 C5303 C5304 C5311 C5376 C5377 C5440 C5484 C5485 C5570	P4524	5	1	D

[4] Schedule 1, entry for Mannitol acid in the form Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers and brand bronchitol

omit from the column headed 'Circumstances' **: C4293 C4294 C4299 C4303** *insert :* **C5658 C5799**

[5] Schedule 1, entry for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg

a) omit from the column headed 'Circumstances' (all instances) **: C5580 C5588**

b) insert in the column headed 'Circumstances' (all instances): **C5626 C5653**

[6] Schedule 1, entry for Mycophenolic acid in each of the forms Tablet containing mycophenolate mofetil 500 mg and Powder for oral suspension containing mycophenolate mofetil 1 g per 5 mL, 165 mL

a) omit from the column headed 'Circumstances' (all instances) **: C5567 C5599**

b) insert in the column headed 'Circumstances' (all instances): **C5794 C5795**

[7] Schedule 1, entry for Octreotide in each of the forms Injection (modified release) 10 mg (as acetate), vial and diluent syringe; Injection (modified release) 20 mg (as acetate), vial and diluent syringe; and Injection (modified release) 30 mg (as acetate), vial and diluent syringe and brand Sandostatin LAR

a) omit from the column headed 'Circumstances' (all instances) : **C4560 C4561 C4563 C4564 C4568 C4571**

b) insert in the column headed 'Circumstances' (all instances) **: C5628 C5654 C5678 C5707 C5737 C5738**

[8] Schedule 1, entry for Sirolimus in each of the forms Tablet 0.5 mg, Tablet 1 mg, Tablet 2 mg, Oral solution 1 mg per mL, 60 mL

omit from the column headed 'Circumstances' : **C5567 C5599** *insert:* **C5794 C5795**

[9] Schedule 1, entry for Tipranavir in the form Capsule 250 mg and brand Aptivus

omit from the column headed 'Circumstances' : **C4981** *insert:* **C5764**

[10] Schedule 1, entry for Zoledronic Acid

substitute:

Zoledronic acid	Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL	Injection	APO-Zoledronic Acid	TX	MP	C5605 C5606 C5676 C5677 C5703 C5704 C5735 C5736	1	11	D
			DBL Zoledronic Acid	HH	MP	C5605 C5606 C5676 C5677 C5703 C5704 C5735 C5736	1	11	D
			Zometa	NV	MP	C5605 C5606 C5676 C5677 C5703 C5704 C5735 C5736	1	11	D
	Solution for I.V. infusion 4 mg (as monohydrate) in 100 mL	Injection	DBL Zoledronic Acid	HH	MP	C5605 C5606 C5676 C5677 C5703 C5704 C5735 C5736	1	11	D
			Zometa	NV	MP	C5605 C5606 C5676 C5677 C5703 C5704 C5735 C5736	1	11	D

[11] Schedule 3, entry for Dornase Alfa

substitute:

Dornase alfa	C5634	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	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5634

	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 or 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. Treatment with this drug 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.	
C5635	Where the patient is receiving treatment at/from a public hospital Cystic fibrosis Treatment Phase: 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 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 this drug 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 5635
C5715	Where the patient is receiving treatment at/from a private hospital Cystic fibrosis Treatment Phase: 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 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 this drug 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
C5740	Where the patient is receiving treatment at/from a public hospital Cystic fibrosis 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 or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, 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. To be eligible for continued PBS-subsidised treatment with this drug 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) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general 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 5740

C5768		Where the patient is receiving treatment at/from a private hospital Cystic fibrosis 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 or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, 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. To be eligible for continued PBS-subsidised treatment with this drug 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) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.	Compliance with Written or Telephone Authority Required procedures
C5800		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 or 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. Treatment with this drug 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

[12] Schedule 3, entry for Everolimus

a) omit:

C5567	P5567	Where the patient is receiving treatment at/from a private hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection,AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures
C5599	P5599	Where the patient is receiving treatment at/from a public hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) The treatment must be under the supervision and direction of a transplant unit, AND The treatment must include initiation, stabilisation, and review of therapy as required.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5599

b) insert:

	C5794	P5794	Where the patient is receiving treatment at/from a private hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures
	C5795	P5795	Where the patient is receiving treatment at/from a public hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5795

[13] Schedule 3, entry for Mannitol

substitute:

Mannitol	C5658	P5658	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 initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, AND Patient must be intolerant or inadequately responsive to dornase alfa. 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 or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, 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 mannitol at a dose of 400 mg twice daily. To be eligible for continued PBS-subsidised treatment with this drug 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) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.	Compliance with Written or Telephone Authority Required procedures
	C5799	P5799	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 initiation dose assessment for this drug, prior to therapy with this drug, with a negative result, AND Patient must be intolerant or inadequately responsive to dornase alfa. 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 or by a specialist physician or paediatrician in consultation with such a unit. Prior to therapy with this drug, 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 mannitol at a dose of 400 mg twice daily. To be eligible for continued PBS-subsidised treatment with this drug 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 - Streamlined Authority Code 5799

	(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient. Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

[14] Schedule 3, entry for Mycophenolic acid

a) omit:

	C5567	P5567	Where the patient is receiving treatment at/from a private hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of cardiac allograft rejection AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures
	C5580	P5580	Where the patient is receiving treatment at/from a public hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) The treatment must be under the supervision and direction of a transplant unit, AND The treatment must include initiation, stabilisation, and review of therapy as required.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5580
	C5588	P5588	Where the patient is receiving treatment at/from a private hospital anagement of renal allograft rejection atment Phase: Management (initiation, stabilisation and review of therapy) treatment must be under the supervision and direction of a transplant unit, AND treatment must include initiation, stabilisation, and review of therapy as required.	Compliance with Written or Telephone Authority Required procedures
	C5599	P5599	Where the patient is receiving treatment at/from a public hospital nagement of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) The treatment must be under the supervision and direction of a transplant unit, AND The treatment must include initiation, stabilisation, and review of therapy as required.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5599

b) insert in numerical order after C5601:

C5626	P5626	Where the patient is receiving treatment at/from a private hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures
C5653	P5653	Where the patient is receiving treatment at/from a public hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5653
C5794	P5794	Where the patient is receiving treatment at/from a private hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures
C5795	P5795	Where the patient is receiving treatment at/from a public hospital Management of renal allograft rejection	Compliance with Written or Telephone Authority Required procedures - Streamlined

			Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Authority Code 5795

[15] Schedule 3, entry Octreotide

a) omit:

	C4560		Where the patient is receiving treatment at/from a private hospital Vasoactive intestinal peptide secreting tumour (VIPoma) Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Written and Telephone Authority Required procedures
	C4561		Where the patient is receiving treatment at/from a public hospital Functional carcinoid tumour Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4561
	C4563		Where the patient is receiving treatment at/from a public hospital Acromegaly The condition must be controlled with octreotide immediate release injections, AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND The treatment must cease if IGF1 is not lower after 3 months of treatment. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4563
	C4564		Where the patient is receiving treatment at/from a public hospital Vasoactive intestinal peptide secreting tumour (VIPoma) Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4564
	C4568		Where the patient is receiving treatment at/from a private hospital Functional carcinoid tumour Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Written and Telephone Authority Required procedures

	C4571		Where the patient is receiving treatment at/from a private hospital Acromegaly The condition must be controlled with octreotide immediate release injections, AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND The treatment must cease if IGF1 is not lower after 3 months of treatment. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Written and Telephone Authority Required procedures

b) insert in numerical order after C3408:

C5628	Where the patient is receiving treatment at/from a private hospital Vasoactive intestinal peptide secreting tumour (VIPoma) Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Written or Telephone Authority Required procedures
C5654	Where the patient is receiving treatment at/from a private hospital Acromegaly The condition must be controlled with octreotide immediate release injections,AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND The treatment must cease if IGF1 is not lower after 3 months of treatment. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Written or Telephone Authority Required procedures
C5678	Where the patient is receiving treatment at/from a public hospital Vasoactive intestinal peptide secreting tumour (VIPoma) Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5678
C5707	Where the patient is receiving treatment at/from a private hospital Functional carcinoid tumour Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Written or Telephone Authority Required procedures

	C5737	Where the patient is receiving treatment at/from a public hospital Acromegaly The condition must be controlled with octreotide immediate release injections, AND The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), AND The treatment must cease if IGF1 is not lower after 3 months of treatment. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5737
	C5738	Where the patient is receiving treatment at/from a public hospital Functional carcinoid tumour Patient must have achieved symptom control on octreotide immediate release injections, AND The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections. Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5738

[16] Schedule 3, entry for Sirolimus

substitute:

Sirolimus	C5794	P5794	Where the patient is receiving treatment at/from a private hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures
	C5795	P5795	Where the patient is receiving treatment at/from a public hospital Management of renal allograft rejection Treatment Phase: Management (initiation, stabilisation and review of therapy) Patient must be receiving this drug for prophylaxis of renal allograft rejection, AND The treatment must be under the supervision and direction of a transplant unit.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5795

[17] Schedule 3, entry for Tipranavir

substitute:

Tipranavir	C5764	P5764	HIV infection The treatment must be in addition to optimised background therapy, AND The treatment must be in combination with other antiretroviral agents, AND Patient must be antiretroviral experienced, AND The treatment must be co-administered with 200 mg ritonavir twice daily, AND Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5764

[18] Schedule 3, entry for Zoledronic acid

substitute:

Zoledronic acid	C5605	P5605	Where the patient is receiving treatment at/from a public hospital Bone metastases The condition must be due to breast cancer.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5605
	C5606	P5606	Where the patient is receiving treatment at/from a private hospital Bone metastases The condition must be due to castration-resistant prostate cancer.	Compliance with Written or Telephone Authority Required procedures
	C5676	P5676	Where the patient is receiving treatment at/from a private hospital Multiple myeloma	Compliance with Written or Telephone Authority Required procedures
	C5677	P5677	Where the patient is receiving treatment at/from a private hospital Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy.	Compliance with Written or Telephone Authority Required procedures
	C5703	P5703	Where the patient is receiving treatment at/from a public hospital Bone metastases The condition must be due to castration-resistant prostate cancer.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5703
	C5704	P5704	Where the patient is receiving treatment at/from a public hospital Hypercalcaemia of malignancy Patient must have a malignancy refractory to anti-neoplastic therapy.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5704
	C5735	P5735	Where the patient is receiving treatment at/from a public hospital Multiple myeloma	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 5735
	C5736	P5736	Where the patient is receiving treatment at/from a private hospital Bone metastases The condition must be due to breast cancer.	Compliance with Written or Telephone Authority Required procedures