



PB 122 of 2010

National Health (Highly specialised drugs program for hospitals) Special Arrangement Amendment Instrument 2010 (No. 1)

National Health Act 1953

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

Dated 15 December 2010

FELICITY MCNEILL
Acting First Assistant Secretary
Pharmaceutical Benefits Division
Department of Health and Ageing

1 Name of Amendment Instrument

- (1) This Amendment Instrument is the *National Health (Highly specialised drugs program for hospitals) Special Arrangement Amendment Instrument 2010 (No.1)*.
- (2) This instrument may also be cited as PB 122 of 2010.

2 Commencement

This Amendment Instrument commences on 1 January 2011.

3 Amendments to PB 116 of 2010

Schedule 1 amends PB 116 of 2010.

Schedule 1 Amendments

[1] section 4, definition of *manufacturer's pack*

omit:

subsection 6 (2) of the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2010*

and insert:

the determination made under paragraph 98B(1)(a) of the Act

[2] subsection 39(1)

omit (all instances):

Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2010

and insert:

the determination made under paragraph 98B(1)(a) of the Act

[3] paragraph 45(2)(a)

omit:

Determination made pursuant to subsection 84BA(2) of the National Health Act 1953

and insert:

the determination made under subsection 84BA(2) of the Act

[4] Schedule 1, entry for Abacavir

omit from the column headed 'Circumstances' (twice occurring):

C1820 C1821 C3309 C3310

and insert:

C3586 C3587 C3588 C3589

[5] Schedule 1, entry for Abacavir with Lamivudine

omit from the column headed 'Circumstances':

C1822 C1823 C3311 C3312

and insert:

C3590 C3591 C3592 C3593

- [6] Schedule 1, entry for Abacavir with Lamivudine and Zidovudine**
omit from the column headed 'Circumstances':

C1822 C1823 C3311 C3312

and insert:

C3590 C3591 C3592 C3593

- [7] Schedule 1, entry for Atanzavir**
omit from the column headed 'Circumstances' (all instances):

C1832 C1833 C3315 C3316

and insert:

C3586 C3587 C3588 C3589

- [8] Schedule 1, entry for Darunavir**
omit from the column headed 'Circumstances' (twice occurring):

C3279 C3335

and insert:

C3594 C3595

- [9] Schedule 1, entry for Didanosine**
omit from the column headed 'Circumstances' (all instances):

C1820 C1821 C3309 C3310

and insert:

C3586 C3587 C3588 C3589

- [10] Schedule 1, entry for Efavirenz**
omit from the column headed 'Circumstances' (all instances):

C1820 C1821 C3309 C3310

and insert:

C3586 C3587 C3588 C3589

- [11] Schedule 1, entry for Emtricitabine**
omit from the column headed 'Circumstances':
 C1820 C1821 C3309 C3310
and insert:
 C3856 C3587 C3588 C3589
- [12] Schedule 1, entry for Enfuvirtide**
omit from the column headed 'Circumstances':
 C2007 C2008 C3350 C3351
and insert:
 C3596 C3597
- [13] Schedule 1, entry for Etravirine**
omit from the column headed 'Circumstances':
 C2956 C3354
and insert:
 C3596 C3597
- [14] Schedule 1, entry for Fosamprenavir in the form Tablet 700 mg (as calcium)**
*omit from the column headed 'Responsible Person' **GK** and insert **VI***
- [15] Schedule 1, entry for Fosemprenavir**
omit from the column headed 'Circumstances' (all instances):
 C1832 C1833 C3315 C3316
and insert:
 C3586 C3587 C3588 C3589
- [16] Schedule 1, entry for Indinavir**
omit from the column headed 'Circumstances':
 C1820 C1821 C3309 C3310
and insert:
 C3586 C3587 C3588 C3589

- [17] Schedule 1, entry for Infliximab**
omit from the column headed 'Circumstances':
 C3006
and insert in the column headed 'Circumstances' in numerical order following the last circumstance:
 C3585
- [18] Schedule 1, entry for Lamivudine in each of the forms: Tablet 150mg; Tablet 300mg; and Oral solution 10mg per mL, 240mL**
omit from the column headed 'Circumstances':
 C1820 C1821 C3309 C3310
and insert:
 C3586 C3587 C3588 C3589
- [19] Schedule 1, entry for Lamivudine with Zidovudine**
omit from the column headed 'Circumstances':
 C1820 C1821 C3309 C3310
and insert:
 C3586 C3587 C3588 C3589
- [20] Schedule 1, entry for Lopinavir with Ritonavir**
omit from the column headed 'Circumstances' (all instances):
 C1832 C1833 C3315 C3316
and insert:
 C3586 C3587 C3588 C3589
- [21] Schedule 1, entry for Maraviroc**
omit from the column headed 'Circumstances' (all instances):
 C3286 C3406
and insert:
 C3598 C3599

- [22] Schedule 1, entry for Nevirapine**
omit from the column headed 'Circumstances' (all instances):
 C1820 C1821 C3309 C3310
and insert:
 C3586 C3587 C3588 C3589
- [23] Schedule 1, entry for Raltegravir**
omit from the column headed 'Circumstances':
 C3505 C3506 C3507 C3508
and insert:
 C3586 C3587 C3588 C3589
- [24] Schedule 1, entry for Ritonavir**
omit from the column headed 'Circumstances' (twice occurring):
 C1820 C1821 C3309 C3310
and insert:
 C3586 C3587 C3588 C3589
- [25] Schedule 1, entry for Saquinavir**
omit from the column headed 'Circumstances':
 C1820 C1821 C3309 C3310
and insert:
 C3586 C3587 C3588 C3589
- [26] Schedule 1, entry for Stavudine**
omit from the column headed 'Circumstances' (all instances):
 C1820 C1821 C3309 C3310
and insert:
 C3586 C3587 C3588 C3589

- [27] Schedule 1, entry for Tenofovir**
omit from the column headed 'Circumstances':
 C1820 C1821 C2931 C3203 C3309 C3310 C3313 C3417
and insert:
 C2931 C3203 C3313 C3417 C3586 C3587 C3588 C3589
- [28] Schedule 1, entry for Tenofovir with Emtricitabine**
omit from the column headed 'Circumstances':
 C1820 C1821 C3309 C3310
and insert:
 C3586 C3587 C3588 C3589
- [29] Schedule 1, entry for Tenofovir with emtricitabine and efavirenz**
omit from the column headed 'Circumstances':
 C1820 C1821 C3309 C3310
and insert:
 C3586 C3587 C3588 C3589
- [30] Schedule 1, entry for Tipranavir in the form Capsule 250mg**
omit from the column headed 'Circumstances':
 C2700 C3418
and insert:
 C3600 C3601
- [31] Schedule 1, entry for Tipranavir in the form Oral liquid 100 mg per mL, 95 mL**
omit from the column headed 'Circumstances':
 C3500 C3501
and insert:
 C3602 C3603

[32] Schedule 1, entry for Zidovudine*omit from the column headed 'Circumstances' (all instances):*

C1820 C1821 C3309 C3310

and insert:

C3586 C3587 C3588 C3589

[32] Schedule 2, after:

PF	Pfizer Australia Pty Ltd	50 008 422 348
----	--------------------------	----------------

omit in the columns in the order indicated:

PF	ViiV Healthcare Pty Ltd	46 138 687 448
----	-------------------------	----------------

[33] Schedule 3, entry for Abacavir*substitute:*

Abacavir	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[34] Schedule 3, entry for Abacavir with Lamivudine*substitute:*

Abacavir with Lamivudine	C3590		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
--------------------------	-------	--	---	--

	C3591		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3592		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3592
	C3593		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3593

[35] Schedule 3, entry for Abacavir with Lamivudine and Zidovudine

substitute:

Abacavir with Lamivudine and Zidovudine	C3590		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3591		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3592		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient over 12 years of age, weighing 40 kg or more, with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3592
	C3593		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3593

[36] Schedule 3, entry for Atazanavir

substitute:

Atazanavir	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures

	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[37] Schedule 3, entry for Darunavir
substitute:

Darunavir	C3594		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus (HIV) infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance 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
	C3595		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus (HIV) infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 100 mg ritonavir twice daily in an antiretroviral experienced patient who, after at least one antiretroviral regimen, has experienced virological failure or clinical failure or genotypic resistance 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 3595

[38] Schedule 3, entry for Didanosine
substitute:

Didanosine	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[39] Schedule 3, entry for Efavirenz*substitute:*

Efavirenz	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[40] Schedule 3, entry for Emtricitabine*substitute:*

Emtricitabine	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[41] Schedule 3, entry for Enfuvirtide*substitute:*

Enfuvirtide	C3596		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus (HIV) infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. 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
	C3597		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus (HIV) infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. 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 3597

[42] Schedule 3, entry for Etravirine*substitute:*

Etravirine	C3596		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus (HIV) infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. 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
	C3597		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus (HIV) infection, in addition to optimised background therapy in combination with other antiretroviral agents in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. 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 3597

[43] Schedule 3, entry for Fosamprenavir*substitute:*

Fosamprenavir	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[44] Schedule 3, entry for Indinavir*substitute:*

Indinavir	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[45] Schedule 3, entry for Infliximab*omit:*

	C3006		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — initial treatment (paediatric patient) Initial PBS-subsidised treatment by a gastroenterologist, paediatrician, consultant physician in	Compliance with modified Authority Required procedures
--	-------	--	---	--

			internal medicine specialising in gastroenterology or consultant physician in general medicine specialising in gastroenterology, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria: (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified above; and (b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if the patient does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; (iii) immunosuppressive therapy including: — azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or — 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or — methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; and where the following conditions apply: if treatment with any of the drugs mentioned at (c) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, the authority application includes details of the contraindication; if intolerance to treatment with the regimens mentioned at (c) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; failure to achieve an adequate response is indicated by severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30, as assessed preferably whilst still on treatment but no longer than 1 month following cessation of the most recent prior treatment, and is demonstrated in the patient at the time of the authority application; the most recent PCDAI assessment is no more than 1 month old at the time of application; all tests and assessments are performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; the application for authorisation is made in writing and includes a completed copy of the appropriate Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and (ii) details of previous systemic drug therapy (dosage, date of commencement and duration of therapy), or dates of enteral nutrition; and (iii) the signed patient acknowledgement; a course of initial treatment is limited to a maximum of 3 doses at 5 mg per kg body weight per dose, to be administered at weeks 0, 2 and 6 of the course; if a supply insufficient for 3 doses is authorised when the written application is made, a subsequent authority application for a supply sufficient to allow the patient to complete the initial course of 3 doses may be submitted by telephone	
--	--	--	---	--

and insert in the columns in the order indicated, and in numerical order for the column headed “Circumstances Code”:

	C3585		Where the patient is receiving treatment at/from a private or public hospital Crohn disease — initial treatment (paediatric patient) Initial PBS-subsidised treatment by a gastroenterologist, paediatrician, consultant physician in internal medicine specialising in gastroenterology or consultant physician in general medicine specialising in gastroenterology, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies the following criteria: (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified above; and (b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if the patient does not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; (iii) immunosuppressive therapy including: — azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or — 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or — methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; and where the following conditions apply: if treatment with any of the drugs mentioned at (c) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, the authority application includes details of the contraindication; if intolerance to treatment with the regimens mentioned at (c) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; failure to achieve an adequate response is indicated by severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30, as assessed preferably whilst still on treatment but no longer than 1 month following cessation of the most recent prior treatment, and is demonstrated in the patient at the time of the authority application; the most recent PCDAI assessment is no more than 1 month old at the time of application; all tests and assessments are performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; the application for authorisation is made in writing and includes a completed copy of the appropriate Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and (ii) details of previous systemic drug therapy (dosage, date of commencement and duration of therapy), or dates of enteral nutrition; and (iii) the signed patient acknowledgement; a course of initial treatment is limited to a maximum of 3 doses at 5 mg per kg body weight per dose, to be administered at weeks 0, 2 and 6 of the course;	Compliance with modified Authority Required procedures
--	-------	--	---	--

			if a supply insufficient for 3 doses is authorised when the written application is made, a subsequent authority application for a supply sufficient to allow the patient to complete the initial course of 3 doses may be submitted by telephone	
--	--	--	--	--

[46] Schedule 3, entry for Lamivudine
substitute:

Lamivudine	C2932		Where the patient is receiving treatment at/from a private hospital Patients with chronic hepatitis B who satisfy all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.	Compliance with Written or Telephone Authority Required procedures
	C3386		Where the patient is receiving treatment at/from a public hospital Patients with chronic hepatitis B who satisfy all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3386
	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[47] Schedule 3, entry for Lamivudine with Zidovudine*substitute:*

Lamivudine with Zidovudine	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[48] Schedule 3, entry for Lopinavir with Ritonavir*substitute:*

Lopinavir with Ritonavir	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[49] Schedule 3, entry for Maraviroc*substitute:*

Maraviroc	C3598		Where the patient is receiving treatment at/from a private hospital Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic human immunodeficiency virus type 1 (HIV-1), who, after each of at least three difference antiretroviral	Compliance with Written or Telephone Authority Required procedures
-----------	-------	--	---	--

			regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible. 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-linking toxicity.	
	C3599		Where the patient is receiving treatment at/from a public hospital Treatment, in addition to optimised background therapy in combination with other antiretroviral agents, of an antiretroviral experienced patient infected with only CCR5-tropic human immunodeficiency virus type 1 (HIV-1), who, after each of at least three difference antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. A tropism assay to determine CCR5 only strain status is required prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible. 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-linking toxicity.	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3599

[50] Schedule 3, entry for Nevirapine
substitute:

Nevirapine	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[51] Schedule 3, entry for Raltegravir
substitute:

Raltegravir	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
-------------	-------	--	---	--

	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[52] Schedule 3, entry for Ritonavir
substitute:

Ritonavir	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[53] Schedule 3, entry for Saquinavir
substitute:

Saquinavir	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588

	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589
--	-------	--	---	--

[54] Schedule 3, entry for Stavudine

substitute:

Stavudine	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[55] Schedule 3, entry for Tenofovir

substitute:

Tenofovir	C2931		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (1)(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or (b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance; (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures
	C3203		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B Treatment, as sole PBS-subsidised therapy, of chronic hepatitis B in a patient who is nucleoside analogue naive and satisfies all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation	Compliance with Written or Telephone Authority Required procedures

			disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	
	C3313		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (1)(a) Repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration in conjunction with documented chronic hepatitis B infection; or (b) Repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months, whilst on previous antihepadnaviral therapy except in patients with evidence of poor compliance; (2) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3313
	C3417		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B Treatment, as sole PBS-subsidised therapy, of chronic hepatitis B in a patient who is nucleoside analogue naive and satisfies all of the following criteria: (1) Histological evidence of chronic hepatitis on liver biopsy (except in patients with coagulation disorders considered severe enough to prevent liver biopsy); (2)(a) Abnormal serum ALT levels in conjunction with documented chronic hepatitis B infection; or (b) Elevated HBV DNA levels in conjunction with documented chronic hepatitis B infection; (3) Female patients of child-bearing age are not pregnant, not breast-feeding, and are using an effective form of contraception. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3417
	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures

	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[56] Schedule 3, entry for Tenofovir with Emtricitabine

substitute:

Tenofovir with Emtricitabine	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[57] Schedule 3, entry for Tenofovir with emtricitabine and efavirenz

substitute:

Tenofovir with Emtricitabine and Efavirenz	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

[58] Schedule 3, entry for Tipranavir
substitute:

Tipranavir	C3600		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus (HIV) infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. 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
	C3601		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus (HIV) infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with 200 mg ritonavir twice daily in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. 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 3601
	C3602		Where the patient is receiving treatment at/from a private hospital Treatment of human immunodeficiency virus (HIV) infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with ritonavir in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. 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
	C3603		Where the patient is receiving treatment at/from a public hospital Treatment of human immunodeficiency virus (HIV) infection, in addition to optimised background therapy in combination with other antiretroviral agents, and co-administered with ritonavir in an antiretroviral experienced patient who, after each of at least three different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes, has experienced virological failure or clinical failure or genotypic resistance. 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 3603

[59] Schedule 3, entry for Zidovudine
substitute:

Zidovudine	C3586		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures
------------	-------	--	---	--

	C3587		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures
	C3588		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3588
	C3589		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3589

Note

All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*.
See <http://www.frli.gov.au>.