



PB 5 of 2012

National Health (Highly specialised drugs program for hospitals) Special Arrangement Amendment Instrument 2012 (No. 1)

National Health Act 1953

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

Dated 16 February 2012

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

1 Name of Instrument

- (1) This Instrument is the *National Health (Highly specialised drugs program for hospitals) Special Arrangement Amendment Instrument 2012 (No.1)*.
- (2) This Instrument may also be cited as PB 5 of 2012.

2 Commencement

This Instrument commences on 1 March 2012.

3 Amendments to PB 116 of 2010

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

Schedule 1 Amendments

[1] Paragraph 24(2)(m)

omit:

PBSsubsidised

substitute:

PBS-subsidised

[2] Subparagraph 45(2)(b)(ii)

omit:

paragraph (a)

substitute:

subparagraph (i)

[3] Schedule 1, entry for Abacavir with Lamivudine and Zidovudine in the form Tablet containing abacavir 300 mg (as sulphate) with lamivudine 150 mg and zidovudine 300 mg

omit from the column headed "Circumstances":

C3590 C3591 C3592 C3593

substitute:

C3979 C3980 C3981 C3982

[4] Schedule 1, entry for Adefovir in the form Tablet containing adefovir dipivoxil 10 mg

omit from the column headed "Circumstances":

C3863 C3864

substitute:

C3971 C3972 C3973 C3974

[5] Schedule 1, after entry for Darunavir in the form Tablet 400 mg (as ethanolate)

insert in the columns in the order indicated:

	Tablet 600 mg (as ethanolate)	Oral	Prezista	JC	EMP	C3594 C3595		120	5	D
--	-------------------------------	------	----------	----	-----	-------------	--	-----	---	---

[6] Schedule 1, entry for Entecavir in the form Tablet containing entecavir monohydrate 0.5 mg

omit from the column headed "Circumstances":

C3871 C3872

substitute:

C3959 C3960 C3961 C3962

[7] Schedule 1, entry for Entecavir in the form Tablet containing entecavir monohydrate 1 mg

omit from the column headed "Circumstances":

C3873 C3874

substitute:

C3963 C3964 C3965 C3966

[8] Schedule 1, after entry for Filgrastim after the form Injection 300 micrograms in 0.5 mL single use pre-filled syringe (Nivestim):

insert in the columns in the order indicated:

	Injection 300 micrograms in 0.5 mL single use pre-filled syringe (TevaGrastim)	Injection	TevaGrastim	AS	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834	20	11	D
--	--	-----------	-------------	----	-----	--	----	----	---

[9] Schedule 1, after entry for Filgrastim after the form Injection 480 micrograms in 0.5 mL single use pre-filled syringe (Nivestim):

insert in the columns in the order indicated:

	Injection 480 micrograms in 0.8 mL single use pre-filled syringe (TevaGrastim)	Injection	TevaGrastim	AS	EMP	C2912 C2913 C2914 C2915 C2916 C2917 C2918 C2919 C2920 C2921 C2922 C2923 C2924 C2925 C2926 C2927 C2928 C2929 C2930 C3087 C3187 C3357 C3358 C3359 C3360 C3361 C3362 C3363 C3364 C3365 C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377 C3833 C3834	20	11	D
--	--	-----------	-------------	----	-----	--	----	----	---

[10] Schedule 1, entry for Foscarnet in the form I.V. infusion containing foscarnet sodium 24 mg per mL, 250 mL

omit from the column headed "Responsible Person":

AP

substitute:

IX

[11] Schedule 1, entry for Interferon Alfa-2a

omit from the column headed "Circumstances" (all instances):

C3869 C3870

substitute:

C3959 C3960 C3961 C3962

[12] Schedule 1, entry for Interferon Alfa-2b

omit from the column headed "Circumstances" (all instances):

C3869 C3870

substitute:

C3959 C3960 C3961 C3962

[13] Schedule 1, entry for Lamivudine in the form Tablet 100 mg

omit from the column headed "Circumstances":

C3871 C3872

substitute:

C3959 C3960 C3961 C3962

[14] Schedule 1, entry for Lamivudine in the form Oral solution 5 mg per mL, 240 mL

omit from the column headed "Circumstances":

C3871 C3872

substitute:

C3959 C3960 C3961 C3962

[15] Schedule 1, entry for Peginterferon Alfa-2a

omit from the column headed "Circumstances" (all instances):

C3867 C3868

substitute:

C3975 C3976 C3977 C3978

[16] Schedule 1, entry for Telbivudine

omit from the column headed "Circumstances":

C3865 C3866

substitute:

C3967 C3968 C3969 C3970

[17] Schedule 1, entry for Tenofovir

omit from the column headed "Circumstances":

C3863 C3864 C3865 C3866

substitute:

C3967 C3968 C3969 C3970 C3971 C3972 C3973 C3974

[18] Schedule 1, entry for Tenofovir with emtricitabine and efavirenz

omit from the column headed "Circumstances":

C3586 C3587 C3588 C3589

substitute:

C3983 C3984 C3985 C3986

[19] Schedule 2, entry for AP

omit:

AP	AstraZeneca Pty Ltd	54 009 682 311
----	---------------------	----------------

[20] Schedule 2, after entry for AN

insert:

AS	Aspen Pharmacare Australia Pty Ltd	51 096 236 985
----	------------------------------------	----------------

[21] Schedule 2, after entry for IS

insert:

IX	Clinect Pty Ltd	76 150 558 473
----	-----------------	----------------

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

substitute:

Abacavir with Lamivudine and Zidovudine	C3979		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection 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 Authority Required procedures
---	-------	--	---	---

	C3980		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection	Compliance with Authority Required procedures
	C3981		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection 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 Authority Required procedures - Streamlined Authority Code 3981
	C3982		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection where the patient over 12 years of age, weighing 40 kg or more, has previously received PBS-subsidised therapy for HIV infection	Compliance with Authority Required procedures - Streamlined Authority Code 3982

[23] Schedule 3, entry for Adefovir

substitute:

Adefovir	C3971		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (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;	Compliance with Authority Required procedures
	C3972		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA. 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 Authority Required procedures
	C3973		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria: (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	Compliance with Authority Required procedures - Streamlined Authority

		evidence of poor compliance	Code 3973
	C3974	<p>Where the patient is receiving treatment at/from a public hospital</p> <p>Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.</p> <p>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</p>	<p>Compliance with Authority Required Procedures - Streamlined Authority Code 3974</p>

[24] Schedule 3, entry for Entecavir

substitute:

Entecavir	C3959	<p>Where the patient is receiving treatment at/from a private hospital</p> <p>Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.</p> <p>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.</p>	Compliance with Authority Required procedures
	C3960	<p>Where the patient is receiving treatment at/from a private hospital</p> <p>Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy;</p>	Compliance with Authority Required procedures
	C3961	<p>Where the patient is receiving treatment at/from a public hospital</p> <p>Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy</p>	Compliance with Authority Required procedures - Streamlined Authority Code 3961
	C3962	<p>Where the patient is receiving treatment at/from a public hospital</p> <p>Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA.</p> <p>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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 3962
	C3963	<p>Where the patient is receiving treatment at/from a private hospital</p> <p>Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria:</p>	Compliance with Authority Required

			(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;	procedures
	C3964		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B Chronic hepatitis B in a patient without cirrhosis who has failed lamivudine and who satisfies all of the following criteria: (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	Compliance with Authority Required procedures - Streamlined Authority Code 3964
	C3965		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B in a patient with cirrhosis who has failed lamivudine and who has detectable HBV DNA. 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 Authority Required procedures
	C3966		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B in a patient with cirrhosis who has failed lamivudine and who has detectable HBV DNA. 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 Authority Required procedures - Streamlined Authority Code 3966

[25] Schedule 3, entry for Interferon Alfa-2a

omit:

	C3869		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B in a patient who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; (3) Is not a person 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).	Compliance with Authority Required procedures
	C3870		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B in a patient who satisfies all of the following criteria:	Compliance with Authority

			(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; (3) Is not a person with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L)	Required procedures - Streamlined Authority Code 3870
--	--	--	--	---

and insert in numerical order following the last circumstance:

	C3959		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. 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 Authority Required procedures
	C3960		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy;	Compliance with Authority Required procedures
	C3961		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy	Compliance with Authority Required procedures - Streamlined Authority Code 3961
	C3962		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. 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 Authority Required procedures - Streamlined Authority Code 3962

[26] Schedule 3, entry for Interferon Alfa-2b

omit:

	C3869		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B in a patient who satisfies all of the following criteria:	Compliance with Authority
--	-------	--	--	---------------------------

			(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; (3) Is not a person 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).	Required procedures
	C3870		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B in a patient who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAG positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAG negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; (3) Is not a person with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L)	Compliance with Authority Required procedures - Streamlined Authority Code 3870

and insert in numerical order following the last circumstance:

	C3959		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. 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 Authority Required procedures
	C3960		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy;	Compliance with Authority Required procedures
	C3961		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy	Compliance with Authority Required procedures - Streamlined Authority Code 3961
	C3962		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. 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	Compliance with Authority Required procedures - Streamlined

			initiating therapy	Authority Code 3962
--	--	--	--------------------	---------------------

[27] Schedule 3, entry for Lamivudine

omit:

	C3871		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B in a patient who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy. 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 Authority Required procedures
	C3872		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B in a patient who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAG positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAG negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy. Persons with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L) should have their treatment discussed with a transplant unit prior to initiating therapy	Compliance with Authority Required procedures - Streamlined Authority Code 3872

and insert in numerical order following the last circumstance:

	C3959		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. 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 Authority Required procedures
	C3960		Where the patient is receiving treatment at/from a private hospital Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy;	Compliance with Authority Required procedures
	C3961		Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B in a patient without cirrhosis who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;	Compliance with Authority Required

		(2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy	procedures - Streamlined Authority Code 3961
	C3962	Where the patient is receiving treatment at/from a public hospital Chronic hepatitis B in a patient with cirrhosis who has detectable HBV DNA. 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 Authority Required procedures - Streamlined Authority Code 3962

[28] Schedule 3, entry for Peginterferon Alfa-2a

omit:

	C3867	Where the patient is receiving treatment at/from a private hospital Monotherapy in a patient with chronic hepatitis B and compensated liver disease who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; (3) Have received no prior peginterferon alfa therapy for the treatment of hepatitis B; (4) Is not a person 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). Treatment is limited to 1 course of treatment for a duration of up to 48 weeks;	Compliance with Authority Required procedures
	C3868	Where the patient is receiving treatment at/from a public hospital Monotherapy in a patient with chronic hepatitis B who and compensated liver disease who satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAG positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAG negative - in conjunction with documented chronic hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy; (3) Have received no prior peginterferon alfa therapy for the treatment of hepatitis B; (4) Is not a person 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). Treatment is limited to 1 course of treatment for a duration of up to 48 weeks	Compliance with Authority Required procedures - Streamlined Authority Code 3868

and insert in numerical order following the last circumstance:

	C3975	Where the patient is receiving treatment at/from a private hospital Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all	Compliance with Authority Required
--	-------	---	------------------------------------

			<p>of the following criteria:</p> <p>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;</p> <p>(2) Evidence of chronic liver injury as determined by:</p> <p>(a) Confirmed elevated serum ALT; or</p> <p>(b) Liver biopsy;</p> <p>(3) Has received no prior peginterferon alfa therapy for the treatment of hepatitis B;</p>	procedures
	C3976		<p>Where the patient is receiving treatment at/from a private hospital</p> <p>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA.</p> <p>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.</p> <p>Treatment is limited to 1 course of treatment for a duration of up to 48 weeks;</p>	Compliance with Authority Required procedures
	C3977		<p>Where the patient is receiving treatment at/from a public hospital</p> <p>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who satisfies all of the following criteria:</p> <p>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented chronic hepatitis B infection;</p> <p>(2) Evidence of chronic liver injury as determined by:</p> <p>(a) Confirmed elevated serum ALT; or</p> <p>(b) Liver biopsy;</p> <p>(3) Has received no prior peginterferon alfa therapy for the treatment of hepatitis B</p>	Compliance with Authority Required procedures - Streamlined Authority Code 3977
	C3978		<p>Where the patient is receiving treatment at/from a public hospital</p> <p>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who has detectable HBV DNA.</p> <p>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.</p> <p>Treatment is limited to 1 course of treatment for a duration of up to 48 weeks</p>	Compliance with Authority Required procedures - Streamlined Authority Code 3978

[29] Schedule 3, entry for Telbivudine

substitute:

Telbivudine	C3967		<p>Where the patient is receiving treatment at/from a private hospital</p> <p>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:</p> <p>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;</p> <p>(2) Evidence of chronic liver injury as determined by:</p> <p>(a) Confirmed elevated serum ALT; or</p> <p>(b) Liver biopsy;</p>	Compliance with Authority Required procedures
-------------	-------	--	--	---

	C3968		<p>Where the patient is receiving treatment at/from a private hospital</p> <p>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.</p> <p>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.</p>	Compliance with Authority Required procedures
	C3969		<p>Where the patient is receiving treatment at/from a public hospital</p> <p>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:</p> <p>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;</p> <p>(2) Evidence of chronic liver injury as determined by:</p> <p>(a) Confirmed elevated serum ALT; or</p> <p>(b) Liver biopsy</p>	Compliance with Authority Required procedures - Streamlined Authority Code 3969
	C3970		<p>Where the patient is receiving treatment at/from a public hospital</p> <p>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.</p> <p>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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 3970

[30] Schedule 3, entry for Tenfovir

omit:

	C3863		<p>Where the patient is receiving treatment at/from a private hospital</p> <p>Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria:</p> <p>(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</p> <p>(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.</p> <p>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.</p>	Compliance with Authority Required procedures
	C3864		<p>Where the patient is receiving treatment at/from a public hospital</p> <p>Chronic hepatitis B</p> <p>Chronic hepatitis B in a patient who has failed antihepadnaviral therapy and who satisfies all of the following criteria:</p> <p>(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</p> <p>(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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 3864

			compliance. 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	
	C3865		Where the patient is receiving treatment at/from a private hospital Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B who is nucleoside analogue naive and satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum; or (b) Liver biopsy. 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 Authority Required procedures
	C3866		Where the patient is receiving treatment at/from a public hospital Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B who is nucleoside analogue naive and satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAG positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAG negative - in conjunction with documented hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum; or (b) Liver biopsy. 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 Authority Required procedures - Streamlined Authority Code 3866

and insert in numerical order following the last circumstance:

	C3967		Where the patient is receiving treatment at/from a private hospital Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria: (1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection; (2) Evidence of chronic liver injury as determined by: (a) Confirmed elevated serum ALT; or (b) Liver biopsy;	Compliance with Authority Required procedures
	C3968		Where the patient is receiving treatment at/from a private hospital Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA. 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 Authority Required procedures
	C3969		Where the patient is receiving treatment at/from a public hospital	Compliance

			<p>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B without cirrhosis who is nucleoside analogue naive and satisfies all of the following criteria:</p> <p>(1) Elevated HBV DNA levels - greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, or greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative - in conjunction with documented hepatitis B infection;</p> <p>(2) Evidence of chronic liver injury as determined by:</p> <p>(a) Confirmed elevated serum ALT; or</p> <p>(b) Liver biopsy</p>	with Authority Required procedures - Streamlined Authority Code 3969
	C3970		<p>Where the patient is receiving treatment at/from a public hospital</p> <p>Treatment, as sole PBS-subsidised therapy, in a patient with chronic hepatitis B with cirrhosis who is nucleoside analogue naive and who has detectable HBV DNA.</p> <p>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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 3970
	C3971		<p>Where the patient is receiving treatment at/from a private hospital</p> <p>Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria:</p> <p>(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</p> <p>(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;</p>	Compliance with Authority Required procedures
	C3972		<p>Where the patient is receiving treatment at/from a private hospital</p> <p>Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.</p> <p>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.</p>	Compliance with Authority Required procedures
	C3973		<p>Where the patient is receiving treatment at/from a public hospital</p> <p>Chronic hepatitis B in a patient without cirrhosis who has failed antihepadnaviral therapy and who satisfies all of the following criteria:</p> <p>(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</p> <p>(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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 3973
	C3974		<p>Where the patient is receiving treatment at/from a public hospital</p> <p>Chronic hepatitis B in a patient with cirrhosis who has failed antihepadnaviral therapy and who has detectable HBV DNA.</p> <p>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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 3974

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

substitute:

Tenofovir with emtricitabine and efavirenz	C3983		Where the patient is receiving treatment at/from a private hospital Initial treatment of human immunodeficiency virus (HIV) infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Authority Required procedures
	C3984		Where the patient is receiving treatment at/from a private hospital Continuing treatment of human immunodeficiency virus (HIV) infection where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Authority Required procedures
	C3985		Where the patient is receiving treatment at/from a public hospital Initial treatment of human immunodeficiency virus (HIV) infection in a patient with a CD4 count of less than 500 per cubic millimetre or symptomatic HIV disease	Compliance with Authority Required procedures - Streamlined Authority Code 3985
	C3986		Where the patient is receiving treatment at/from a public hospital Continuing treatment of human immunodeficiency virus (HIV) infection where the patient has previously received PBS-subsidised therapy for HIV infection	Compliance with Authority Required procedures - Streamlined Authority Code 3986

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>.