PB 28 of 2011

National Health (Highly specialised drugs program for hospitals) Special Arrangement Amendment Instrument 2011 (No. 3)

National Health Act 1953

I, LINDA JACKSON, Assistant Secretary, Access and Systems Branch, 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 28 March 2011

LINDA JACKSON
Assistant Secretary
Access and Systems Branch
Pharmaceutical Benefits Division
Department of Health and Ageing

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1 Name of Instrument

(1) This Instrument is the *National Health (Highly specialised drugs program for hospitals) Special Arrangement Amendment Instrument 2011 (No.3).*

(2) This Instrument may also be cited as PB 28 of 2011.

2 Commencement

This Instrument commences on 1 April 2011.

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)

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Schedule 1 Amendments

[1] Section 4, definition of CAR drug:

omit (a) to (n) and insert:

(a) abatacept;
(b) adalimumab;
(c) ambrisentan;
(d) azacitidine;
(e) bosentan;
(f) epoprostenol;
(g) etanercept;
(h) iloprost;
(i) infliximab;
(j) lenalidomide;
(k) rituximab;
(l) romiplostin;
(m) sildenafil; and
(n) tocilizumab.

[2] Paragraph 24(2)(a), after iloprost

omit:

, sildenafil or sitaxentan

and insert:

or sildenafil

[3] Subsection 24(2), after paragraph 24(2)(j)

insert:

(k) for HSD pharmaceutical benefits that have the drug romiplostin, for initial treatment of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP):

(i) at the time of the initial written authority application – a quantity of units that are sufficient, based on the weight of the patient, to provide for a single dose of 1 microgram per kilogram;

(ii) during the initial period of dose titration – a quantity of units sufficient to provide for a single dose;

(iii) for a patient whose dose has been stable for a period of 4 weeks – a quantity of units that are sufficient, based on the weight of the patient and the dose, for up to 4 weeks of treatment, as long as the total period of treatment that has been authorised does not exceed 24 weeks.

(l) for HSD pharmaceutical benefits that have the drug romiplostin, for initial PBS-subsidised treatment of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostin prior to 1 April 2011 and in whom the criteria for initial treatment in the circumstances can be demonstrated to have been met at the time his or her treatment with romiplostin was commenced:

(i) at the time of the initial written authority application – a quantity of units that are sufficient, based on the weight of the patient, to provide for a single dose of 1 microgram per kilogram;

(ii) during the initial period of dose titration – a quantity of units sufficient to provide for a single dose;

(iii) for a patient in the titration phase of treatment whose dose has been stable for a period of 4 weeks – a quantity of units that are sufficient, based on the weight of the patient and the dose, for up to 4 weeks of treatment, as long as the total period of treatment that has been authorised does not exceed 24 weeks;

(iv) for a patient whose dose had been stable for a period of at least 4 weeks at the time of the initial application for PBS-subsidy – a quantity of units that are sufficient, based on the weight of the patient and the dose, for up to 4 weeks of treatment.

(m) for HSD pharmaceutical benefits that have the drug romiplostin, for the first period of continuing treatment or re-initiation of interrupted PBS-subsidised treatment of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostin during the initial period of PBS-subsidised treatment – a quantity of units that are sufficient, based on the weight of the patient and the dose, for up to 4 weeks treatment.

(n) for HSD pharmaceutical benefits that have the drug romiplostin, for the second and subsequent periods of continuing treatment of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who continues to display a sustained platelet response to treatment with romiplostin – a quantity of units that are sufficient, based on the weight of the patient and the dose, for up to 4 weeks of treatment.

[4] Paragraph 25(2)(l), after iloprost

omit:

, sildenafil or sitaxentan

insert:

or sildenafil

[5] Subsection 25(2), after paragraph 25(2)(o)

insert:

(p) for romiplostin for initial treatment of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP):

(i) at the time of the initial written authority application – 1 repeat supply;

(ii) during the initial period of dose titration – 1 repeat supply;

(iii) for a patient whose dose has been stable for a period of 4 weeks – up to 4 repeat supplies.

(q) for romiplostin for initial PBS-subsidised treatment of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostin prior to 1 April 2011 and in whom the criteria for initial treatment in the circumstances can be demonstrated to have been met at the time his or her treatment with romplostin was commenced:

(i) at the time of the initial written authority application – 1 repeat supply;

(ii) during the initial period of dose titration – 1 repeat supply;

(iii) for a patient in the titration phase of treatment whose dose has been stable for a period of 4 weeks – up to 4 repeat supplies;

(iv) for a patient whose dose had been stable for a period of at least 4 weeks at the time of the initial application for PBS-subsidy – up to 5 repeat supplies.

(r) for romiplostin for the first period of continuing treatment or re-initiation of interrupted PBS-subsidised treatment of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpure (ITP) who has displayed a sustained platelet response to treatment with romiplostin during the initial period of PBS-subsidised treatment:

(i) at the time of the initial written authority application – up to 5 repeat supplies;

(ii) where less than 5 repeat supplies are requested in the initial written authority application – sufficient repeat supplies to complete a maximum of 24 weeks treatment.

(s) for romiplostin for the second and subsequent periods of continuing treatment of severe thrombocytopenia in an adult with severe chronic immune (idiopathic) thrombocytopenic purpure (ITP) who continues to display a sustained platelet response to treatment with romiplostin – up to 5 repeat supplies.

[6] Schedule 1, entry for Ambrisentan

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

C3213

[7] Schedule 1, entry for Filgrastim

substitute:

Filgrastim	Injection 300 micrograms in 1 mL	Injection	Neupogen	AN	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		20	11	D
	Injection 300 micrograms in 0.5 mL single use pre-filled syringe (Neupogen)	Injection	Neupogen	AN	EMP	C2912 C2913 C2914 C2915		20	11	D

						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				
	Injection 300 micrograms in 0.5 mL single use pre-filled syringe (Nivestim)	Injection	Nivestim	HH	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		20	11	D

						C3374 C3375 C3376 C3377				
	Injection 480 micrograms in 1.6 mL	Injection	Neupogen	AN	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		20	11	D
	Injection 480 micrograms in 0.5 mL single use pre-filled syringe (Neupogen)	Injection	Neupogen	AN	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		20	11	D

						C3366 C3367 C3368 C3369 C3370 C3371 C3372 C3373 C3374 C3375 C3376 C3377				
	Injection 480 micrograms in 0.5 mL single use pre-filled syringe (Nivestim)	Injection	Nivestim	HH	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		20	11	D

[8] Schedule 1, entry for Infliximab

omit from the column headed 'Circumstances':

C3452 C3453 C3454 C3455

and insert in the column headed 'Circumstances' in numerical order following the last circumstance:

C3691 C3692 C3693 C3694

[9] Schedule 1, after entry for Rituximab

insert:

Romiplostin	Powder for injection 375 micrograms	Injection	Nplate	AN	EMP	C3699 C3700 C3701 C3702		See Note 1	See Note 2	D

	Powder for injection 625 micrograms	Injection	Nplate	AN	EMP	C3699 C3700 C3701 C3702		See Note 1	See Note 2	D

[10] Schedule 1, omit entry for Sitaxentan

[11] Schedule 1, entry for Valaciclovir

substitute:

Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	APO-Valaciclovir	TX	EMP	C1494 C3419		500	2	C
			Valtrex	GK	EMP	C1494 C3419		500	2	C

[12] Schedule 3, entry for Ambrisentan

omit:

	C3213		Where the patient is receiving treatment at/from a private or public hospital Initial treatment (previous treatment not PBS-subsidised) Initial PBS-subsidised treatment with ambrisentan of patients who were receiving treatment with ambrisentan prior to 1 December 2009 and who have been assessed by a physician from a designated hospital to have: (a) World Health Organisation (WHO) Functional Class III primary pulmonary hypertension; or (b) WHO Functional Class III pulmonary arterial hypertension secondary to connective tissue disease; or (c) WHO Functional Class IV primary pulmonary hypertension; or (d) WHO Functional Class IV pulmonary arterial hypertension secondary to connective tissue disease; and where the following conditions apply: the authority application is made in writing and includes: (1) for patients who have received less than 6 months of ambrisentan treatment at the time of application — a completed copy of the appropriate Pulmonary Arterial Hypertension PBS Authority Application – Supporting Information form which includes results from a right heart catheterisation (RHC) composite assessment plus echocardiography (ECHO) composite assessment plus 6 minute walk test (6MWT) at the time treatment with ambrisentan was commenced, or, where results from all 3 of the tests are not available or it was not possible on clinical grounds to perform all 3 of the tests, from 1 of the following combinations of tests which are listed in order of decreasing acceptability: (i) RHC composite assessment plus ECHO composite assessment; or (ii) RHC composite assessment plus 6MWT; or (iii) RHC composite assessment alone; or (iv) ECHO composite assessment plus 6MWT; or (v) ECHO composite assessment alone; and (2) the date of commencement of ambrisentan treatment; and (3) a signed patient acknowledgment indicating that the patient understands and acknowledges that PBS-subsidised treatment with a PAH agent will cease if the treating physician determines that the patient has not achieved a response to treatment; and (4) where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test or tests could not be conducted; for patients who have received less than 6 months of non-PBS-subsidised ambrisentan treatment at the time of application — the maximum duration of treatment which will be authorised under this criterion is sufficient to allow the patient to complete a total of 6 months of combined PBS-subsidised and non-PBS-subsidised therapy; if the duration of treatment authorised for the written application under this criterion is less than that to which the patient is entitled, subsequent authority applications under this criterion for supplies sufficient to enable the patient to complete the maximum allowable duration of treatment may be submitted by telephone; determination of a quantity of the drug sufficient to provide 1 month of therapy is based on the dosage recommendations in the TGA-approved Product Information	Compliance with modified Authority Required procedures

[13] Schedule 3, entry for Infliximab

omit:

	C3452		Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — initial treatment Initial PBS-subsidised treatment with infliximab, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology or a consultant physician in general medicine specialising in gastroenterology, of a patient with complex refractory fistulising Crohn disease who: (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) has an externally draining enterocutaneous or rectovaginal fistula; and (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and where the following conditions apply: the authority application is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) a signed patient acknowledgement; the most recent fistula assessment is no more than 1 month old at the time of application; 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, subsequent authority applications for supplies sufficient to enable the patient to complete the initial course of 3 doses may be submitted by telephone	Compliance with modified Authority Required procedures
	C3453		Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — recommencement of PBS-subsidised treatment Re-initiation of PBS-subsidised treatment of complex refractory fistulising Crohn disease, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology or a consultant physician in general medicine specialising in gastroenterology, of a patient with complex refractory fistulising Crohn disease who: (a) has a documented history of complex refractory fistulising Crohn disease; and (b) has an externally draining enterocutaneous or rectovaginal fistula; and (c) has previously received PBS-subsidised infliximab treatment for a draining enterocutaneous or rectovaginal fistula; and (d) either: (i) has demonstrated or sustained an adequate response to the most recent course of PBS-subsidised treatment with infliximab for this condition; or (ii) has failed to demonstrate or sustain an adequate response to PBS-subsidised treatment with infliximab for this condition and 12 months have elapsed from the date on which treatment was ceased; and where the following conditions apply: the authority application is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition; the most recent fistula assessment is no more than 1 month old at the time of application; a course re-initiating PBS-subsidised 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, subsequent authority applications for supplies sufficient to enable the patient to complete the initial course of 3 doses may be submitted by telephone; a patient who fails to respond to a course of PBS-subsidised infliximab for the treatment of complex refractory fistulising Crohn disease is not eligible to receive further PBS-subsidised treatment with infliximab for this condition within 12 months of the date on which treatment was ceased	Compliance with modified Authority Required procedures
	C3454		Where the patient is receiving treatment at/from a private or public hospital	Compliance

			Fistulising Crohn disease — initial PBS-subsidised treatment (previous infliximab treatment non-PBS-subsidised) Initial PBS-subsidised supply for continuing treatment with infliximab, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology, a consultant physician in general medicine specialising in gastroenterology, or other consultant physician in consultation with a gastroenterologist, of a patient who satisfies the following criteria: (a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and (b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (d) is receiving treatment with infliximab at the time of application; and (e) has demonstrated or sustained an adequate response to treatment with infliximab; and where the following conditions apply: an adequate response to infliximab treatment is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient; the application for authorisation is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment form including the date of assessment of the patient's condition; and (ii) a signed patient acknowledgement; the current fistula assessment is no more than 1 month old at the time of application; the baseline fistula assessment is from immediately prior to commencing treatment with infliximab; the course of treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone; a patient is eligible for PBS-subsidised treatment under this restriction once only	with modified Authority Required procedures
	C3455		Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — continuing treatment Continuing PBS-subsidised treatment with infliximab, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology, a consultant physician in general medicine specialising in gastroenterology, or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of complex refractory fistulising Crohn disease; and (b) has demonstrated or sustained an adequate response to treatment with infliximab; and where the following conditions apply: an adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient; the authority application is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition; the fistula assessment is no more than 1 month old at the time of application; the assessment of the patient's response to a course of treatment is provided to the Medicare Australia CEO no later than 4 weeks from the date of completion of the course, and, if the course of treatment is a 3 dose initial course, the assessment is made up to 12 weeks after the first dose (up to 6 weeks following the third dose); where an assessment is not submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab; a course of continuing treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone; patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the	Compliance with modified Authority Required procedures

			response	

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

	C3691		Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — initial treatment 1 Initial treatment commencing a treatment cycle, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology or a consultant physician in general medicine specialising in gastroenterology, of a patient with complex refractory fistulising Crohn disease who: (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) has an externally draining enterocutaneous or rectovaginal fistula; and (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for fistulising Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: the authority application is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) a signed patient acknowledgement; the most recent fistula assessment is no more than 1 month old at the time of application; a course of initial treatment commencing a treatment cycle 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, subsequent authority applications for supplies sufficient to enable the patient to complete the initial course of 3 doses may be submitted by telephone	Compliance with modified Authority Required procedures
	C3692		Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — initial treatment 2 (change or recommencement of PBS-subsidised treatment) Initial treatment, or recommencement of treatment, with infliximab within an ongoing treatment cycle, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology or a consultant physician in general medicine specialising in gastroenterology, of a patient with complex refractory fistulising Crohn disease who: (a) has a documented history of complex refractory fistulising Crohn disease; and (b) in this treatment cycle, has received prior PBS-subsidised treatment with adalimumab or infliximab for a draining enterocutaneous or rectovaginal fistula; and (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for fistulising Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where TNF-alfa antagonist means adalimumab or infliximab; and where the following conditions apply: the authority application is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and	Compliance with modified Authority Required procedures

			(ii) details of prior TNF-alfa antagonist treatment including details of date and duration of treatment; the most recent fistula assessment is no more than 1 month old at the time of application; to demonstrate a response to treatment the application must be accompanied by the results of the patient's most recent course of TNF-alfa antagonist therapy; the assessment of response to the most recent course of TNF-alfa antagonist therapy must: (a) be provided to the Medicare Australia CEO no later than 4 weeks from the date that course was ceased; and (b) have been made following a minimum of 12 weeks of treatment if the course of therapy was a 16-week initial course of adalimumab, and up to 12 weeks after the first dose (6 weeks following the third dose) if the course of therapy was a 3 dose initial course of infliximab; if the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist; a course of initial treatment within an ongoing treatment cycle 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, subsequent authority applications for supplies sufficient to enable the patient to complete the initial course of 3 doses may be submitted by telephone	
	C3693		Where the patient is receiving treatment at/from a private or public hospital Fistulising Crohn disease — initial treatment 3 (previous infliximab treatment non-PBS-subsidised) Commencement of a treatment cycle with an initial PBS-subsidised course of infliximab for continuing treatment, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology, a consultant physician in general medicine specialising in gastroenterology, or other consultant physician in consultation with a gastroenterologist, of a patient who satisfies the following criteria: (a) has a documented history of complex refractory fistulising Crohn disease and was receiving treatment with infliximab prior to 1 March 2010; and (b) had a draining enterocutaneous or rectovaginal fistula(e) prior to commencing treatment with infliximab; and (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criteria for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and (d) is receiving treatment with infliximab at the time of application; and (e) has demonstrated or sustained an adequate response to treatment with infliximab; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for fistulising Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response to infliximab treatment is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient; the application for authorisation is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) a completed current and baseline Fistula Assessment form including the date of assessment of the patient's condition; and (ii) a signed patient acknowledgement; the current fistula assessment is no more than 1 month old at the time of application; the baseline fistula assessment is from immediately prior to commencing treatment with infliximab; the course of treatment is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone; a patient is eligible for PBS-subsidised treatment under this restriction once only	Compliance with modified Authority Required procedures
	C3694		Where the patient is receiving treatment at/from a private or public hospital	Compliance

			Fistulising Crohn disease — continuing treatment Continuing PBS-subsidised treatment with infliximab within an ongoing treatment cycle, by a gastroenterologist, a consultant physician in internal medicine specialising in gastroenterology, a consultant physician in general medicine specialising in gastroenterology, or other consultant physician in consultation with a gastroenterologist, of a patient who: (a) has a documented history of complex refractory fistulising Crohn disease; and (b) has demonstrated or sustained an adequate response to treatment with infliximab; and where a treatment cycle is a period of treatment which commences when an eligible patient (one who has not received PBS-subsidised treatment with adalimumab or infliximab for fistulising Crohn disease in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with adalimumab or infliximab, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised courses of treatment with adalimumab or infliximab up to 3 times (but with the same drug no more than twice), at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply: an adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient; the authority application is made in writing and includes a completed copy of the appropriate Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition; the fistula assessment is no more than 1 month old at the time of application; the assessment of the patient's response to a course of treatment is provided to the Medicare Australia CEO no later than 4 weeks from the date of completion of the course, and, if the course of treatment is a 3 dose initial course, the assessment is made up to 12 weeks after the first dose (up to 6 weeks following the third dose); where an assessment is not submitted to the Medicare Australia CEO within the timeframes specified above, the patient will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab; a course of continuing treatment within an ongoing treatment cycle is limited to a maximum of 24 weeks of treatment; if less than 24 weeks of treatment is authorised when the written application is made, subsequent authority applications for supplies sufficient to enable the patient to complete a course of 24 weeks of treatment in total may be submitted by telephone; patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response	with modified Authority Required procedures

[14] Schedule 3, after entry for Rituximab

insert:

Romiplostin	C3699		Where the patient is receiving treatment at/from a private or public hospital Initial (new patients) Initial treatment of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is: (1) Splenectomised and: (a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and (b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy; or (2) Not splenectomised and: (a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and (b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and (c) in whom splenectomy is contraindicated for medical reasons. The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application: (a) a platelet count of less than or equal to 20,000 million per L; or (b) a platelet count of 20,000 million-30,000 million per L, where the patient is experiencing significant bleeding or has a history of	Compliance with modified Authority Required procedures

			significant bleeding in this platelet range. The authority application must be made in writing and must include: (1) a completed authority prescription form, (2) a signed patient acknowledgement, (3) a completed Romiplostin PBS Authority Application - Supporting Information Form, (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated. The full blood count must be no more than 1 month old at the time of application. At the time of the written authority application, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application. Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone. The dose (microgram/kg/week) must be provided at the time of application. Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks. Authority approval will not be given for doses of higher than 10 micrograms/kg/week	
	C3700		Where the patient is receiving treatment at/from a private or public hospital Initial (grandfather patients) Initial PBS-subsidised treatment of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with romiplostin prior to 1 April 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time romiplostin was commenced. The authority application must be made in writing and must include: (1) a completed authority prescription form, (2) a signed patient acknowledgement, (3) a completed Romiplostin PBS Authority Application - Supporting Information Form, and (4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated. For patients whose dose of romiplostin had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Where the patient is in the titration phase of treatment with romiplostin, medical practitioners should request the appropriate quantity of vials of appropriate strength to provide sufficient drug for a single treatment at a dose of 1 microgram/kg. Up to 1 repeat may be requested with the initial written application. Subsequently during the initial period of dose titration, authority applications for a single dose and up to 1 repeat may be made by telephone. The dose (microgram/kg/week) must be provided at the time of application.	Compliance with modified Authority Required procedures

			Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment and up to 4 repeats may be granted, as long as the total period of treatment authorised under this restriction does not exceed 24 weeks. For patients whose dose of romiplostin had been stable for at least 4 weeks at the time of the initial application for PBS-subsidy, the medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide up to 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Authority approval will not be given for doses of higher than 10 micrograms/kg/week	
	C3701		Where the patient is receiving treatment at/from a private or public hospital Continuing therapy or re-initiation after a break in therapy First period of PBS-subsidised continuing treatment or re-initiation of interrupted PBS-subsidised treatment of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with romiplostin during the initial period of PBS-subsidised treatment. For the purposes of this restriction, a sustained platelet response is defined as use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS-subsidised romiplostin, and either of the following: (a) a platelet count greater than or equal to 50,000 million per L on at least four occasions, each at least one week apart; or (b) a platelet count greater than 30,000 million per L and which is double the baseline (pre-treatment) platelet count on at least four occasions, each at least one week apart. Applications for the first period of continuing PBS-subsidised treatment or re-initiation of interrupted treatment must be made in writing and must include: (1) a completed authority prescription form, (2) a completed Romiplostin PBS Authority Application - Supporting Information Form, and (3) copies of the platelet count pathology reports (unless previously provided for patients re-initiating therapy). The most recent platelet count must be no more than one month old at the time of application. The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone. Authority approval will not be given for doses of higher than 10 micrograms/kg/week	Compliance with modified Authority Required procedures
	C3702		Where the patient is receiving treatment at/from a private or public hospital Second and subsequent applications for continuing therapy Continuing treatment of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously received PBS-subsidised therapy with romiplostin and who continues to display a response to treatment with romiplostin. For the purposes of this restriction, a continuing response to treatment with romiplostin is defined as use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS-subsidised treatment with romiplostin, and either of the following: (a) a platelet count greater than or equal to 50,000 million per L; or (b) a platelet count greater than 30,000 million per L and which is double the baseline platelet count. Platelet counts must be no more than 1 month old at the time of application.	Compliance with modified Authority Required procedures

			Authority applications for second and subsequent periods of continuing therapy may be made by telephone. The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised. Authority approval will not be given for doses of higher than 10 micrograms/kg/week	

[15] **Schedule 3, omit entry for Sitaxentan**

[16] **Schedule 4, entry for Cyclosporin**

substitute:

Cyclosporin	Capsule 25 mg	Oral	Neoral 25	30	38.39	0
	Capsule 50 mg	Oral	Neoral 50	30	79.88	80.94
	Capsule 100 mg	Oral	Neoral 100	30	162.77	164.16

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.