



**PB 14 of 2011**

# **National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2011 (No. 3)<sup>1</sup>**

*National Health Act 1953*

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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 Instrument under sections 84AF, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 18 February 2011

**FELICITY McNEILL**

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

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**1 Name of Instrument**

(1) This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2011 (No. 3)*.

(2) This Instrument may also be cited as PB 14 of 2011.

**2 Commencement**

(1) Sections 1 to 3 and Schedule 1 to this Instrument are taken to have commenced on 1 February 2011.

(2) Schedule 2 to this Instrument commences on 1 March 2011.

**3 Amendment of PB 108 of 2010**

Schedules 1 and 2 amend PB 108 of 2010.

# Schedule 1 Amendments

[1] Schedule 1, entry for Valaciclovir in the form Tablet 500 mg (as hydrochloride)  
*substitute:*

Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	Valtrex	GK	MP NP	C3622 C3631 C3632 C3633	P3632	20	0	
			Zelitrex	RE	MP NP	C3622 C3631 C3632 C3633	P3632	20	0	
			Valtrex	GK	MP NP	C3622 C3631 C3632 C3633	P3633	30	5	
			Zelitrex	RE	MP NP	C3622 C3631 C3632 C3633	P3633	30	5	
			Valtrex	GK	MP NP	C3622 C3631 C3632 C3633	P3622 P3631	42	0	
			Zelitrex	RE	MP NP	C3622 C3631 C3632 C3633	P3622 P3631	42	0	
			Valtrex	GK	MP	C1494 C3419		500	2	C
						See Note 1				

## Schedule 2 Amendments

- [1] **Schedule 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe**  
(a) *omit from the column headed "Circumstances" (all instances):*  
**C3269**  
**C3271**  
(b) *omit from the column headed "Purposes":*  
**P3269**  
**P3271**
- [2] **Schedule 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen**  
(a) *omit from the column headed "Circumstances" (all instances):*  
**C3269**  
**C3271**  
(b) *omit from the column headed "Purposes":*  
**P3269**  
**P3271**
- [3] **Schedule 1, entry for Amino acid formula with vitamins and minerals without lysine and low in tryptophan**  
*omit from the column headed "Form":*  
Sachets containing oral powder 20 g, 30 (GA gel)  
*substitute:*  
Sachets containing oral powder 24 g, 30 (GA gel)

- [4] **Schedule 1, after entry for Amino acid formula with vitamins and minerals without lysine and low in tryptophan in the form Oral powder 500 g (XLYS, LOW TRY Maxamaid)**

*insert as next entry in the columns in the order indicated:*

	Sachets containing oral powder 25 g, 30 (GA express)	Oral	GA express	VF	MP NP	C3678		4	5	
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- [5] **Schedule 1, entry for Amino acid formula with vitamins and minerals without methionine**

*omit from the column headed "Form":*

Sachets containing oral powder 20 g, 30 (HCU gel)

*substitute:*

Sachets containing oral powder 24 g, 30 (HCU gel)

- [6] **Schedule 1, entry for Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine**

*omit from the column headed "Form":*

Sachets containing oral powder 20 g, 30 (MMA/PA gel)

*substitute:*

Sachets containing oral powder 24 g, 30 (MMA/PA gel)

- [7] **Schedule 1, entry for Amino acid formula with vitamins and minerals without phenylalanine**

(a) *omit from the column headed "Form":*

Sachets containing oral powder 20 g, 30 (PKU-gel)

*substitute:*

Sachets containing oral powder 24 g, 30 (PKU gel)

(b) *omit from the column headed "Brand":* **PKU-gel** *and substitute* **PKU gel**

- [8] **Schedule 1, after entry for Amino acid formula with vitamins and minerals without phenylalanine in the form Sachets containing oral powder 50 g, 30 (XP Maxamum)**

*insert in the columns in the order indicated:*

	Oral gel 85 g, 30 (PKU squeezie)	Oral	PKU squeezie	VF	MP NP	C1286		4	5	
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**[9] Schedule 1, entry for Amino acid formula with vitamins and minerals without phenylalanine and tyrosine**

*omit from the column headed "Form":*

Sachets containing oral powder 20 g, 30 (TYR gel)

*substitute:*

Sachets containing oral powder 24 g, 30 (TYR gel)

**[10] Schedule 1, entry for Amino acid formula with vitamins and minerals without valine, leucine and isoleucine**

**(a)** *omit from the column headed "Form":*

Sachets containing oral powder 20 g, 30 (MSUD-gel)

*substitute:*

Sachets containing oral powder 24 g, 30 (MSUD gel)

**(b)** *omit from the column headed "Brand":* **MSUD-gel** *and substitute* **MSUD gel**

**[11] Schedule 1, after entry for Arginine with carbohydrate in the form Sachets of oral powder 4 g containing 500 mg arginine, 30 (Arginine Amino Acid Supplement)**

*insert in the columns in the order indicated:*

Sachets of oral powder 4 g containing 2 g arginine, 30 (Arginine 2000 Amino Acid Supplement)	Oral	Arginine 2000 Amino Acid Supplement	VF	MP NP	C1458		4	5	
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**[12] Schedule 1, entry for "BCG Immunotherapeutic" (Bacillus Calmette-Guérin/Connaught strain)**

*omit from the column headed "Form":*

Single dose set comprising 1 vial powder for intravesical administration containing 6.6 to 19.2 x 10<sup>8</sup> CFU and 1 vial diluent 3 mL

*substitute:*

Powder for intravesical administration containing 6.6 to 19.2 x 10<sup>8</sup> CFU

**[13] Schedule 1, entry for Bicalutamide**

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

**C3247**

*substitute:*

**C3674**

**[14] Schedule 1, entry for Bisoprolol in the form Tablet containing bisoprolol fumarate 2.5 mg**

*substitute:*

Bisoprolol	Tablet containing bisoprolol fumarate 2.5 mg	Oral	Bicard 2.5	SI	MP NP	C3234		28	5	
			Bicor	AL	MP NP	C3234		28	5	
			Bisoprolol Sandoz	SZ	MP NP	C3234		28	5	
			Bispro 2.5	AF	MP NP	C3234		28	5	

**[15] Schedule 1, entry for Bisoprolol in the form Tablet containing bisoprolol fumarate 5 mg**

*substitute:*

Bisoprolol	Tablet containing bisoprolol fumarate 5 mg	Oral	Bicard 5	SI	MP NP	C3234		28	5	
			Bicor	AL	MP NP	C3234		28	5	
			Bisoprolol Sandoz	SZ	MP NP	C3234		28	5	
			Bispro 5	AF	MP NP	C3234		28	5	

**[16] Schedule 1, entry for Bisoprolol in the form Tablet containing bisoprolol fumarate 10 mg**

*substitute:*

Bisoprolol	Tablet containing bisoprolol fumarate 10 mg	Oral	Bicard 10	SI	MP NP	C3234		28	5	
			Bicor	AL	MP NP	C3234		28	5	
			Bisoprolol Sandoz	SZ	MP NP	C3234		28	5	
			Bispro 10	AF	MP NP	C3234		28	5	

**[17] Schedule 1, entry for Bleomycin**

*omit:*

			Blenoxane	BQ	MP See Note 1	C1139 C1198		10	0	
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**[18] Schedule 1, entry for Bortezomib**

**(a)** *omit from the column headed "Circumstances" (twice occurring):*

**C3195 C3196 C3197**

*substitute:*

**C3196 C3681 C3682 C3683 C3684 C3685**

**(b)** *omit from the column headed "Purposes":*

**P3197**

*substitute:*

**P3682 P3685**

**(c)** *omit from the column headed "Purposes":*

**P3195 P3196**

*substitute:*

**P3196 P3681 P3683 P3684**

**[19] Schedule 1, entry for Cephalexin in the form Capsule 250 mg (anhydrous)**

**(a)** *omit:*

			Cephabell	BF	PDP			20	0	
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**(b)** *omit:*

			Cephabell	BF	MP NP MW			20	1	
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**[20] Schedule 1, entry for Cinacalcet in each of the forms: Tablet 30 mg (as hydrochloride); Tablet 60 mg (as hydrochloride); and Tablet 90 mg (as hydrochloride)**

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

**C3023 C3024**

*substitute:*

**C3672 C3673**

(b) omit from the column headed "Purposes" (all instances)

**P3023 P3024**

substitute:

**P3672 P3673**

**[21] Schedule 1, after entry for Citalopram**

insert in the columns in the order indicated:

Citrulline with carbohydrate	Sachets of oral powder 4 g containing 1 g citrulline, 30 (Citrulline 1000 Amino Acid Supplement)	Oral	Citrulline 1000 Amino Acid Supplement	VF	MP NP	C3679		4	5	
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**[22] Schedule 1, entry for Codeine**

omit from the column headed "Authorised Prescriber": **MP PDP** and substitute: **MP NP PDP**

**[23] Schedule 1, entry for Diazepam in the form Tablet 2 mg**

substitute:

Diazepam	Tablet 2 mg	Oral	Antenex 2	AF	MP NP PDP	P3656	50	0		
					MP NP		50	0		
			Ranzepam	RA	MP NP PDP		50	0		
					MP NP		P3656	50		0
			Valium	RO	MP NP PDP		50	0		
					MP NP		P3656	50		0
			Valpam 2	SI	MP NP PDP		50	0		
					MP NP		P3656	50		0
			Antenex 2	AF	MP NP		P3655	50		3
			Ranzepam	RA	MP NP		P3655	50		3
			Valium	RO	MP NP		P3655	50		3
			Valpam 2	SI	MP NP		P3655	50		3

**[24] Schedule 1, after entry for Docetaxel in the form Solution concentrate for I.V. infusion 20 mg in 1 mL**

*insert in the columns in the order indicated:*

Solution concentrate for I.V. infusion 20 mg in 2 mL	Injection	DBL Docetaxel Concentrated Injection	HH	MP See Note 1	C1194 C1742 C2416 C2439 C2732 C3051 C3292 C3428	P3051	1	0	
		Docetaxel Ebewe	IT	MP See Note 1	C1194 C1742 C2416 C2439 C2732 C3051 C3292 C3428	P3051	1	0	
		DBL Docetaxel Concentrated Injection	HH	MP See Note 1	C1194 C1742 C2416 C2439 C2732 C3051 C3292 C3428	P1194 P1742 P2416 P2439 P2732 P3292 P3428	2	0	
		Docetaxel Ebewe	IT	MP See Note 1	C1194 C1742 C2416 C2439 C2732 C3051 C3292 C3428	P1194 P1742 P2416 P2439 P2732 P3292 P3428	2	0	

**[25] Schedule 1, after entry for Docetaxel in the form Solution concentrate for I.V. infusion 80 mg in 4 mL**

*insert in the columns in the order indicated:*

Solution concentrate for I.V. infusion 80 mg in 8 mL	Injection	DBL Docetaxel Concentrated Injection	HH	MP See Note 1	C1194 C1742 C2416 C2439 C2732 C3051 C3292 C3428		1	0	
		Docetaxel Ebewe	IT	MP See Note 1	C1194 C1742 C2416 C2439 C2732 C3051 C3292 C3428		1	0	

**[26] Schedule 1, entry for Enalapril in each of the forms: Tablet containing enalapril maleate 5 mg; Tablet containing enalapril maleate 10 mg; and Tablet containing enalapril maleate 20 mg**

*omit:*

		Enalabell	BF	MP NP			30	5	
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[27] **Schedule 1, entry for Erlotinib in each of the forms: Tablet 25 mg (as hydrochloride); Tablet 100 mg (as hydrochloride); and Tablet 150 mg (as hydrochloride)**

*omit from the column headed "Circumstances":*

**C2973**

[28] **Schedule 1, entry for Exenatide in each of the forms: Injection solution 5 micrograms per dose in pre-filled pen, 60 doses; and Injection solution 10 micrograms per dose in pre-filled pen, 60 doses**

*omit from the column headed "Circumstances":*

**C3535 C3536 C3537 C3538**

*substitute:*

**C3536 C3538 C3676 C3677**

[29] **Schedule 1, entry for Flutamide**

*omit from the column headed "Circumstances" (twice occurring):*

**C3247**

*substitute:*

**C3674**

[30] **Schedule 1, entry for Gabapentin in the form Tablet 800 mg**

*omit:*

			Pendine 800	AF	MP NP	C2664		100	5	
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[31] **Schedule 1, entry for Lercanidipine in each of the forms: Tablet containing lercanidipine hydrochloride 10 mg; and Tablet containing lercanidipine hydrochloride 20 mg**

*insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

			Zircol	AF	MP NP			28	5	
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[32] **Schedule 1, entry for Mesalazine in the form Sachet containing prolonged release granules, 1 g per sachet**

*omit from the column headed "Max Quantity":*     **100**     *and substitute:*     **120**

- [33] Schedule 1, entry for Methadone in each of the forms: Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 200 mL; and Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 1 L

omit from the column headed "Brand": **Sigma Pharmaceuticals (Australia) Pty Ltd** and substitute: **Sigma Methadone Syrup**

- [34] Schedule 1, entry for Mirtazapine in the form Tablet 45 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

			Axit 45	AF	MP NP	C1211		30	5	
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- [35] Schedule 1, entry for Naltrexone in the form Tablet containing naltrexone hydrochloride 50 mg

omit:

			Naltrexone QP	XF	MP NP	C1135		30	1	
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- [36] Schedule 1, entry for Nilutamide

omit from the column headed "Circumstances":

**C3299 C3300**

substitute:

**C3300 C3675**

- [37] Schedule 1, entry for Norfloxacin

substitute:

Norfloxacin	Tablet 400 mg	Oral	Chem mart Norfloxacin	CH	MP NP	C1002 C1070		14	1	
			GenRx Norfloxacin	GX	MP NP	C1002 C1070		14	1	
			Norflohexal	SZ	MP NP	C1002 C1070		14	1	
			Norfloxacin-GA	GM	MP NP	C1002 C1070		14	1	
			Noroxin	MK	MP NP	C1002 C1070		14	1	
			Nufloxib	AF	MP NP	C1002 C1070		14	1	
			Roxin	SI	MP NP	C1002 C1070		14	1	
			Terry White Chemists Norfloxacin	TW	MP NP	C1002 C1070		14	1	

**[38] Schedule 1, entry for Ondansetron**

*substitute:*

Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron ODT-DRLA	RZ	MP NP See Note 1	C3050 C3611 See Note 2	P3050 See Note 2	4 See Note 2	0 See Note 2
					MP NP	C3050 C3611	P3611	10	1
	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron ODT-DRLA	RZ	MP NP See Note 1	C3050 C3611 See Note 2	P3050 See Note 2	4 See Note 2	0 See Note 2
					MP NP	C3050 C3611	P3611	10	1
	Tablet 4 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP NP See Note 1	C3050 C3611 See Note 2	P3050 See Note 2	4 See Note 2	0 See Note 2
			Ondansetron-DRLA	RZ	MP NP See Note 1	C3050 C3611 See Note 2	P3050 See Note 2	4 See Note 2	0 See Note 2
			Ondaz	SZ	MP NP See Note 1	C3050 C3611 See Note 2	P3050 See Note 2	4 See Note 2	0 See Note 2
			Onsetron 4	ZP	MP NP See Note 1	C3050 C3611 See Note 2	P3050 See Note 2	4 See Note 2	0 See Note 2
			Zofran	GK	MP NP See Note 1	C3050 C3611 See Note 2	P3050 See Note 2	4 See Note 2	0 See Note 2
			APO-Ondansetron	TX	MP NP	C3050 C3611	P3611	10	1
			Ondansetron-DRLA	RZ	MP NP	C3050 C3611	P3611	10	1
			Ondaz	SZ	MP NP	C3050 C3611	P3611	10	1
			Onsetron 4	ZP	MP NP	C3050 C3611	P3611	10	1
			Zofran	GK	MP NP	C3050 C3611	P3611	10	1
	Tablet 8 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP NP See Note 1	C3050 C3611 See Note 2	P3050 See Note 2	4 See Note 2	0 See Note 2
			Ondansetron-DRLA	RZ	MP NP See Note 1	C3050 C3611 See Note 2	P3050 See Note 2	4 See Note 2	0 See Note 2
			Ondaz	SZ	MP NP See Note 1	C3050 C3611 See Note 2	P3050 See Note 2	4 See Note 2	0 See Note 2
			Onsetron 8	ZP	MP NP See Note 1	C3050 C3611 See Note 2	P3050 See Note 2	4 See Note 2	0 See Note 2
			Zofran	GK	MP NP See Note 1	C3050 C3611 See Note 2	P3050 See Note 2	4 See Note 2	0 See Note 2

	Wafer 4 mg	Oral	APO-Ondansetron	TX	MP NP	C3050 C3611	P3611	10	1		
			Ondansetron-DRLA	RZ	MP NP	C3050 C3611	P3611	10	1		
			Ondaz	SZ	MP NP	C3050 C3611	P3611	10	1		
			Onsetron 8	ZP	MP NP	C3050 C3611	P3611	10	1		
			Zofran	GK	MP NP	C3050 C3611	P3611	10	1		
			Ondaz Zydis	SZ	MP NP	C3050 C3611	P3050	4	0	See Note 2	
	Wafer 8 mg	Oral		Zofran Zydis	GK	MP NP	C3050 C3611	P3050	4	0	See Note 2
				Ondaz Zydis	SZ	MP NP	C3050 C3611	P3611	10	1	
				Zofran Zydis	GK	MP NP	C3050 C3611	P3611	10	1	
				Ondaz Zydis	SZ	MP NP	C3050 C3611	P3050	4	0	See Note 2
				Zofran Zydis	GK	MP NP	C3050 C3611	P3050	4	0	See Note 2
				Ondaz Zydis	SZ	MP NP	C3050 C3611	P3611	10	1	
	Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL	Oral		Zofran Zydis	GK	MP NP	C3050 C3611	P3611	10	1	
				Zofran syrup 50mL	GK	MP NP	C3050 C3611	P3050	1	0	See Note 2
	I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL	Injection		Ondansetron-Claris	AE	MP NP	C3050 C3611	See Note 2	1	0	See Note 2
				Ondaz	SZ	MP NP	C3050 C3611	See Note 2	1	0	See Note 2
				Onsetron	ZP	MP NP	C3050 C3611	See Note 2	1	0	See Note 2
				Pfizer Australia Pty Ltd	PF	MP NP	C3050 C3611	See Note 2	1	0	See Note 2
				Zofran	GK	MP NP	C3050 C3611	See Note 2	1	0	See Note 2

	I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL	Injection	Ondansetron-Claris	AE	MP NP See Note 1	C3050 C3611 See Note 2	See Note 2	1 See Note 2	0 See Note 2	
			Ondaz	SZ	MP NP See Note 1	C3050 C3611 See Note 2	See Note 2	1 See Note 2	0 See Note 2	
			Onsetron	ZP	MP NP See Note 1	C3050 C3611 See Note 2	See Note 2	1 See Note 2	0 See Note 2	
			Pfizer Australia Pty Ltd	PF	MP NP See Note 1	C3050 C3611 See Note 2	See Note 2	1 See Note 2	0 See Note 2	
			Zofran	GK	MP NP See Note 1	C3050 C3611 See Note 2	See Note 2	1 See Note 2	0 See Note 2	

**[39] Schedule 1, entry for Palonosetron**

*omit from the column headed "Authorised Prescriber":* **MP** *and substitute:* **MP NP**

**[40] Schedule 1, entry for Pindolol in the form Tablet 5 mg**

*omit:*

			Visken 5	NV	MP NP			100	5	
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**[41] Schedule 1, entry for Ranitidine in the form Tablet 150 mg (as hydrochloride)**

*omit:*

			Ranihexal	HX	MP NP MW			60	5	
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**[42] Schedule 1, entry for Salbutamol in the form Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 30**

*omit:*

			Pfizer Australia Pty Ltd	PF	MP NP	C1754 C1755		2	5	
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**[43] Schedule 1, entry for Sumatriptan in the form Tablet 50 mg (as succinate)**

*insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":*

			Sumatriptan generichealth	GQ	MP NP	C3233		4	5	
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**[44] Schedule 1, entry for Tramadol in the form Tablet (sustained release) containing tramadol hydrochloride 100 mg**

*omit from the column headed "Brand":* **Tramahexal SR** *and substitute:* **Tramadol Sandoz SR**

**[45] Schedule 1, entry for Ustekinumab**

**(a)** *omit from the column headed "Circumstances" (twice occurring):*

**C3252**

**C3254**

**(b)** *omit from the column headed "Purposes":*

**P3252**

**P3254**

**[46] Schedule 1, entry for Vildagliptin**

*omit from the column headed "Authorised Prescriber":* **MP** *and substitute:* **MP NP**

**[47] Schedule 4, Part 1, entry for Adalimumab**

**(a)** *omit:*

	C3269	P3269	<p>Chronic plaque psoriasis (whole body) — initial treatment 3            Commencement of a Biological Treatment Cycle with an initial PBS-subsidised course of adalimumab for continuing treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:</p> <p>(a) have a documented history of severe chronic plaque psoriasis and were receiving treatment with adalimumab prior to 1 March 2009; and            (b) had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with adalimumab; and            (c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment of psoriasis affecting the whole body; and            (d) have demonstrated a response as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with adalimumab of psoriasis affecting the whole body; and</p> <p>where biological agent means adalimumab, etanercept, infliximab or ustekinumab; and            where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which</p>	Compliance with Written Authority Required procedures
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			<p>continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and</p> <p>where the following conditions apply:</p> <p>the application for authorisation is made in writing and includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition at baseline (prior to initiation of adalimumab therapy) and the most recent PASI assessment; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and</p> <p>(iii) the signed patient and prescriber acknowledgements;</p> <p>the most recent PASI assessment is no more than 1 month old at the time of application;</p> <p>the course of treatment is limited to a maximum of 24 weeks of treatment;</p> <p>patients are eligible for PBS-subsidised treatment under the above criteria once only</p>	
			<p>Continuation of a course of initial PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis and were receiving non-PBS-subsidised treatment with adalimumab prior to 1 March 2009, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial PBS-subsidised treatment with adalimumab for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total</p>	<p>Compliance with Written or Telephone Authority Required procedures</p>

**(b)** *omit:*

	C3271	P3271	<p>Chronic plaque psoriasis (face, hand, foot) — initial treatment 3</p> <p>Commencement of a Biological Treatment Cycle with an initial PBS-subsidised course of adalimumab for continuing treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:</p> <p>(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, and were receiving treatment with adalimumab prior to 1 March 2009; and</p> <p>(b) whose disease, prior to treatment with adalimumab, was classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot, where either at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe, or the skin area affected was 30% or more of the face, palm of a hand or sole of a foot; and</p> <p>(c) who have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment of psoriasis affecting the face, hand or foot; and</p>	<p>Compliance with Written Authority Required procedures</p>
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			<p>(d) who have demonstrated a response as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with adalimumab of psoriasis affecting the face, hand or foot; and  where biological agent means adalimumab, etanercept, infliximab or ustekinumab; and  where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and  where the following conditions apply:  the application for authorisation is made in writing and includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:  (i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of adalimumab therapy) and the most recent PASI assessment; and  (ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and  (iii) the signed patient and prescriber acknowledgements;  the most recent PASI assessment is no more than 1 month old at the time of application;  the PASI assessment is performed on the same affected body area as assessed at baseline or prior to initiation of adalimumab treatment;  the course of treatment is limited to a maximum of 24 weeks of treatment;  patients are eligible for PBS-subsidised treatment under the above criteria once only</p>	
			Continuation of a course of initial PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot and were receiving non-PBS-subsidised treatment with adalimumab prior to 1 March 2009, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial PBS-subsidised treatment with adalimumab for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total	Compliance with Written or Telephone Authority Required procedures

**[48] Schedule 4, Part 1, entry for Amino acid formula with vitamins and minerals without lysine and low in tryptophan**

*insert after existing text in the columns in the order indicated:*

	C3678		A patient aged 3 years or older with proven glutaric aciduria type 1	
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**[49] Schedule 4, Part 1, entry for Bicalutamide**

*substitute:*

Bicalutamide	C3674		Metastatic (equivalent to stage D) prostatic carcinoma, when used in combination with gonadotrophin-releasing hormone (luteinising hormone-releasing hormone) analogue therapy	Compliance with Authority Required procedures - Streamlined Authority Code 3674
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**[50] Schedule 4, Part 1, entry for Bortezomib**

*substitute:*

Bortezomib	C3196	P3196	<p>Continuing PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has previously received 4 treatment cycles of bortezomib and who, at the time of application, has demonstrated at least a partial response to bortezomib; and where the following conditions apply:</p> <p>if serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:</p> <p>(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or</p> <p>(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours;</p> <p>if serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:</p> <p>(c) at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels;</p> <p>if serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:</p> <p>(d) at least a 50% reduction in bone marrow plasma cells; or</p> <p>(e) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or</p> <p>(f) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. magnetic resonance imaging or computed tomography scan); or</p> <p>(g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L;</p> <p>the same parameters provided for the diagnosis of progressive disease are used to</p>	Compliance with Written Authority Required procedures
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			<p>demonstrate at least a partial response to treatment;</p> <p>a patient is eligible for continuing PBS-subsidised bortezomib treatment beyond 4 cycles if they have achieved at least a partial response at the completion of cycle 4, and the results of the response assessment are included in the application for authorisation of further treatment;</p> <p>where a response assessment is not submitted to the Medicare Australia CEO prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib;</p> <p>the authority application is made in writing not later than 6 months after the application for initial treatment and includes:</p> <p>(1) a completed copy of the appropriate Multiple Myeloma Authority Application - Supporting Information Form; and</p> <p>(2) diagnostic reports, which are no more than 1 month old at the time of application, demonstrating that the patient has achieved at least a partial response;</p> <p>patients who fail to demonstrate at least a partial response after 8 cycles are not eligible to receive further PBS-subsidised treatment with bortezomib;</p> <p>a patient is eligible to receive no more than 2 cycles of treatment beyond the cycle at which a complete response, confirmed by 2 determinations a minimum of 6 weeks apart, was first achieved</p>	
	C3681	P3681	<p>Initial treatment with PBS-subsidised bortezomib</p> <p>Initial PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of a patient with a histological diagnosis of multiple myeloma who has progressive disease after at least 1 prior therapy, who has undergone or is ineligible for a primary stem cell transplant and who has experienced treatment failure after a trial of at least 4 weeks of thalidomide at a dose of at least 100 mg daily or who has failed to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease; and</p> <p>where progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing, or the development of a new, soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause);</p> <p>where oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein and less than 200 mg per 24 hour Bence-Jones proteinuria;</p> <p>where thalidomide treatment failure is defined as:</p> <p>(1) confirmed disease progression during thalidomide treatment or within 6 months of</p>	Compliance with Written Authority Required procedures

		<p>discontinuing thalidomide treatment; or</p> <p>(2) severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment; where severe intolerance due to thalidomide is defined as unacceptable somnolence or sedation interfering with activities of daily living; where toxicity from thalidomide is defined as peripheral neuropathy (Grade 2 or greater, interfering with function), drug-related seizures, serious Grade 3 or Grade 4 drug-related dermatological reactions, such as Stevens-Johnson Syndrome, or other Grade 3 or 4 toxicity; where failure to achieve at least a minimal response after 8 or more weeks of thalidomide-based therapy for progressive disease is defined as:</p> <p>(1) less than a 25% reduction in serum or urine M protein; or</p> <p>(2) in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels; and</p> <p>where the following conditions apply:</p> <p>the patient is not receiving concomitant PBS-subsidised lenalidomide;</p> <p>the authority application is made in writing and includes:</p> <p>(1) a completed copy of the appropriate Multiple Myeloma Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and</p> <p>(2) duration of thalidomide and daily dose prescribed; and</p> <p>(3) a signed patient acknowledgment;</p> <p>if the dosing requirement for thalidomide cannot be met, the authority application states the reasons why this criterion cannot be satisfied;</p> <p>to enable confirmation of eligibility by the Medicare Australia CEO, current diagnostic reports of at least 1 of the following are required:</p> <p>(a) the level of serum M protein (monoclonal protein); or</p> <p>(b) Bence-Jones proteinuria — the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination, i.e. magnetic resonance imaging or computed tomography scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration;</p> <p>as these parameters will be used to determine response, results of the above diagnostic reports must be provided with the authority application as follows:</p> <p>(i) for all patients, results for (a) or (b) or (c) must be provided;</p> <p>(ii) where the patient has oligo-secretory or non-secretory multiple myeloma, (c) or (d) or if relevant (e), (f) or (g) must be provided;</p> <p>where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (either previous or current serum M protein less than 10 g per L</p>	
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			and urinary Bence-Jones protein undetectable or less than 200 mg per 24 hours) must be provided	
	C3682	P3682	<p>Continuing PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has previously received 8 treatment cycles with bortezomib and who, at the time of application, has demonstrated at least a partial response to bortezomib but who has not received 2 treatment cycles after first achieving a confirmed complete response; and</p> <p>where the following conditions apply:</p> <p>if serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:</p> <p>(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or</p> <p>(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours;</p> <p>if serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:</p> <p>(c) the difference between involved and uninvolved serum free light chain (FLC) levels, with at least a 50% reduction in this value;</p> <p>if serum M protein and urine Bence-Jones protein levels and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:</p> <p>(d) at least a 50% reduction in bone marrow plasma cells; or</p> <p>(e) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or</p> <p>(f) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. magnetic resonance imaging or computed tomography scan); or</p> <p>(g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L;</p> <p>the same parameters provided for the diagnosis of progressive disease are used to demonstrate at least a partial response to treatment;</p> <p>a patient is eligible for continuing PBS-subsidised bortezomib treatment beyond 8 cycles if they have achieved at least a partial response at the completion of cycle 8, and the results of the response assessment are included in the application for authorization of further treatment;</p> <p>where a response assessment is not submitted to the Medicare Australia CEO prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib;</p> <p>the authority application is made in writing not later than 10 months after the application for initial treatment and includes:</p> <p>(1) a completed copy of the appropriate Multiple Myeloma Authority Application - Supporting Information Form; and</p> <p>(2) diagnostic reports, which are no more than 1 month old at the time of application, demonstrating that the patient has achieved at least a partial response;</p> <p>a patient is eligible to receive no more than 2 cycles of treatment beyond the cycle at which a complete response, confirmed by 2 determinations a minimum of 6 weeks apart, was first achieved;</p> <p>PBS-subsidised treatment with bortezomib is limited to a maximum of 11 cycles per treatment course</p>	Compliance with Written Authority Required procedures

	C3683	P3683	<p>Retreatment of a patient who has been previously treated with PBS-subsidised bortezomib Initial PBS-subsidised treatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of a patient with multiple myeloma who has progressive disease and who has been previously treated with PBS-subsidised bortezomib. The patient must have experienced at least a partial response to the most recent course of PBS-subsidised bortezomib therapy.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause)</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein and less than 200 mg per 24 hour Bence-Jones proteinuria.</p> <p>If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to re-treatment with bortezomib) is defined as:</p> <p>(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or</p> <p>(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours</p> <p>If serum M protein and Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:</p> <p>(c) the difference between involved and uninvolved serum free light chain (FLC) levels, with at least a 50% reduction in this value</p> <p>If serum M protein and urine Bence-Jones protein levels and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:</p> <p>(d) at least a 50% reduction in bone marrow plasma cells; or</p> <p>(e) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or</p> <p>(f) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. magnetic resonance imaging or computed tomography scan); or</p> <p>(g) normalization of corrected serum calcium to less than or equal to 2.65 mmol per L.</p> <p>The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment.</p> <p>Bortezomib will only be subsidised for patients with multiple myeloma who are not receiving concomitant PBS-subsidised lenalidomide</p>	Compliance with Written Authority Required procedures
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			<p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Multiple Myeloma Authority Application - Supporting Information Form which includes details of the basis of the current diagnosis of progressive disease and nomination of which disease activity parameters will be used to assess response; and</p> <p>(3) diagnostic reports demonstrating the patient has achieved at least a partial response to the most recent course of PBS-subsidised bortezomib, if not previously provided to the Medicare Australia CEO</p> <p>To enable confirmation by the Medicare Australia CEO, current diagnostic reports of at least one of the following are required:</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria — the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. magnetic resonance imaging or computed tomography scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (either previous or current serum M protein less than 10 g per L and urinary Bence-Jones protein undetectable or less than 200 mg per 24 hours) must be provided; and</p> <p>(4) a signed patient acknowledgment</p>	
	C3684	P3684	<p>Continuing retreatment of a patient who has been previously treated with PBS-subsidised bortezomib</p> <p>Continuing PBS-subsidised retreatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has received 4 treatment cycles of bortezomib in the current treatment course and who, at the time of application, has demonstrated at least a partial response to bortezomib</p> <p>If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:</p> <p>(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or</p> <p>(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours</p> <p>If serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:</p> <p>(c) at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels</p> <p>If serum M protein and urine Bence-Jones protein and serum FLC are</p>	Compliance with Written Authority Required procedures

			<p>unmeasurable/unavailable, partial response compared with baseline is defined as:</p> <p>(d) at least a 50% reduction in bone marrow plasma cells; or</p> <p>(e) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or</p> <p>(f) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. magnetic resonance imaging or computed tomography scan); or</p> <p>(g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.</p> <p>For the purpose of assessing eligibility for continuing the current course of PBS-subsidised bortezomib treatment beyond 4 cycles, the patient must have achieved at least a partial response at the completion of cycle 4. The results of the response assessment must be included in a written application to the Medicare Australia CEO for further treatment. Where a response assessment is not submitted to the Medicare Australia CEO prior to cycle 5, patients will be deemed to have failed to respond to treatment with bortezomib. Continuing PBS-subsidised supply will not be approved if there is a gap of more than 6 months between the initial application and subsequent applications</p> <p>The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Multiple Myeloma Authority Application - Supporting Information Form; and</p> <p>(3) diagnostic reports demonstrating the patient has achieved at least a partial response.</p> <p>Diagnostic reports must be no more than 1 month old at the time of application</p> <p>Patients who fail to demonstrate at least a partial response after 8 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib</p> <p>No more than 2 cycles of treatment beyond the cycle at which a confirmed complete response was first achieved will be authorised. Confirmation requires 2 determinations a minimum of 6 weeks apart</p>	
	C3685	P3685	<p>Continuing retreatment of a patient who has been previously treated with PBS-subsidised bortezomib</p> <p>Continuing PBS-subsidised retreatment, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide, of multiple myeloma in a patient who has received 8 treatment cycles with bortezomib in the current treatment course and who, at the time of application, has demonstrated at least a partial response to bortezomib but who has not received 2 treatment cycles after first achieving a confirmed complete response</p> <p>If serum M protein and urine Bence-Jones protein levels are measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as:</p> <p>(a) at least a 50% reduction in the level of serum M protein (monoclonal protein); or</p> <p>(b) at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours</p> <p>If serum M protein and urine Bence-Jones protein levels are unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as:</p> <p>(c) the difference between involved and uninvolved serum free light chain (FLC) levels, with at least a 50% reduction in this value</p>	Compliance with Written Authority Required procedures

			<p>If serum M protein and urine Bence-Jones protein levels and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:</p> <p>(d) at least a 50% reduction in bone marrow plasma cells; or</p> <p>(e) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or</p> <p>(f) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. magnetic resonance imaging or computed tomography scan); or</p> <p>(g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.</p> <p>The same parameters provided for the diagnosis of progressive disease are to be used to demonstrate at least a partial response to treatment</p> <p>Diagnostic reports must be within 1 month of the date of application.</p> <p>For the purpose of assessing eligibility for continuing PBS-subsidised bortezomib treatment beyond 8 cycles, the patient must have achieved at least a partial response at the completion of cycle 8. The results of the response assessment must be included in a written application to the Medicare Australia CEO for further treatment. Where a response assessment is not submitted to the Medicare Australia CEO prior to cycle 9, patients will be deemed to have failed to respond to treatment with bortezomib. Continuing PBS-subsidised supply will not be approved if there is a gap of more than 10 months between the initial application and an application following completion of 8 treatment cycles</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Multiple Myeloma Authority Application - Supporting Information Form; and</p> <p>(3) diagnostic reports demonstrating the patient has achieved at least a partial response.</p> <p>No more than 2 cycles of treatment beyond the cycle at which the complete response was first achieved will be authorised. Confirmation requires 2 determinations a minimum of 6 weeks apart</p> <p>Applications for PBS-subsidised treatment with bortezomib that extends beyond 11 cycles per treatment course will not be approved</p>	
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**[51] Schedule 4, Part 1, entry for Cinacalcet**

*substitute:*

Cinacalcet	C2893		Where the patient is receiving treatment at/from a private hospital Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with intact parathyroid hormone (iPTH) of at least 50 pmol per L, not responding to conventional therapy	Compliance with Written or Telephone Authority Required procedures
	C2894		Where the patient is receiving treatment at/from a private hospital Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with intact parathyroid hormone (iPTH) of at least 15 pmol per L and less than 50 pmol per L and an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional	Compliance with Written or Telephone Authority Required procedures

			treatment	
	C3323		Where the patient is receiving treatment at/from a public hospital Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with intact parathyroid hormone (iPTH) of at least 50 pmol per L, not responding to conventional therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3323
	C3324		Where the patient is receiving treatment at/from a public hospital Management, including initiation and stabilisation, by a nephrologist, of a patient with chronic kidney disease on dialysis who has sustained secondary hyperparathyroidism with intact parathyroid hormone (iPTH) of at least 15 pmol per L and less than 50 pmol per L and an (adjusted) serum calcium concentration at least 2.6 mmol per L, not responding to conventional treatment	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 3324
	C3672	P3672	Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has intact parathyroid hormone (iPTH) greater than 15 pmol per L and an (adjusted) serum calcium concentration of less than 2.6 mmol per L after 6 months treatment	Compliance with Authority Required procedures - Streamlined Authority Code 3672
	C3673	P3673	Maintenance therapy, following initiation and stabilisation of treatment with cinacalcet, of a patient with chronic kidney disease on dialysis who has a decrease of at least 30% in intact parathyroid hormone (iPTH) concentrations after 6 months treatment	Compliance with Authority Required procedures - Streamlined Authority Code 3673

**[52] Schedule 4, Part 1, after entry for Citalopram**

*insert in the columns in the order indicated:*

Citrulline with carbohydrate	C3679		Urea cycle disorders in order to prevent low plasma arginine or citrulline levels	
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**[53] Schedule 4, Part 1, entry for Erlotinib**

*omit:*

	C2973		Initial PBS-subsidised treatment, as monotherapy, in a patient with locally advanced or metastatic (stage IIIB or IV) non-small cell lung cancer, after prior treatment with platinum-based chemotherapy: (1) where: (a) disease progression occurred following treatment with docetaxel or pemetrexed; or (b) treatment with docetaxel and pemetrexed was either contraindicated or could not be tolerated; and (2) who has received treatment with erlotinib under the Erlotinib Access Programme prior to 1 August 2008; and (3) who does not have progressive disease	Compliance with Authority Required procedures
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**[54] Schedule 4, Part 1, entry for Exenatide**

*substitute:*

Exenatide	C3536		Continuation of therapy, in combination with either metformin or a sulfonylurea, in a patient with type 2 diabetes where the patient has previously been issued with an authority prescription for exenatide	Compliance with Authority Required procedures
	C3538		Continuation of therapy, in combination with metformin and a sulfonylurea, in a patient with type 2 diabetes where the patient has previously been issued with an authority prescription for exenatide	Compliance with Authority Required procedures
	C3676		Initiation of therapy, in combination with either metformin or a sulfonylurea, in a patient with type 2 diabetes in whom a combination of metformin and a sulfonylurea is contraindicated or not tolerated, and: (a) who has a glycosylated haemoglobin (HbA1c) level greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1; or (b) as an alternative to HbA1c level measurement in the case of patients who have clinical conditions with reduced red blood cell survival (including haemolytic anaemias and haemoglobinopathies) and/or who have had red cell transfusion within the previous 3 months — where blood glucose monitoring over a 2 week period prior to initiation of a gliptin, a glitazone or a glucagon-like peptide-1 shows blood glucose levels greater than 10 mmol per L in more than 20% of tests; and where the HbA1c level and date of measurement, or the results of the blood glucose monitoring, whichever are applicable in the circumstances, are documented in the patient's medical records at the time therapy with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated; and where the HbA1c level and the results of the blood glucose monitoring are no more than 4	Compliance with Authority Required procedures

			months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated	
	C3677		Initiation of therapy, in combination with metformin and a sulfonylurea, in a patient with type 2 diabetes who, despite maximally tolerated doses of metformin and a sulfonylurea, has: (a) a glycosylated haemoglobin (HbA1c) level greater than 7% prior to initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone) or a glucagon-like peptide-1; or (b) as an alternative to HbA1c level measurement in the case of patients who have clinical conditions with reduced red blood cell survival (including haemolytic anaemias and haemoglobinopathies) and/or who have had red cell transfusion within the previous 3 months — blood glucose levels greater than 10 mmol per L in more than 20% of tests conducted during blood glucose monitoring over a 2 week period prior to initiation of a gliptin, a glitazone or a glucagon-like peptide-1; and where the HbA1c level and date of measurement, or the results of the blood glucose monitoring, whichever are applicable in the circumstances, are documented in the patient's medical records at the time therapy with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated; and where the HbA1c level and the results of the blood glucose monitoring are no more than 4 months old at the time treatment with a gliptin, a glitazone or a glucagon-like peptide-1 is initiated	Compliance with Authority Required procedures

**[55] Schedule 4, Part 1, entry for Flutamide**

*substitute:*

Flutamide	C3674		Metastatic (equivalent to stage D) prostatic carcinoma, when used in combination with gonadotrophin-releasing hormone (luteinising hormone-releasing hormone) analogue therapy	Compliance with Authority Required procedures - Streamlined Authority Code 3674
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**[56] Schedule 4, Part 1, entry for Nilutamide**

*substitute:*

Nilutamide	C3300		Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, when used in conjunction with surgical orchidectomy	Compliance with Authority Required procedures - Streamlined
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				Authority Code 3300
	C3675		Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) prostatic carcinoma, when used in combination with gonadotrophin-releasing hormone (luteinising hormone-releasing hormone) analogue therapy	Compliance with Authority Required procedures - Streamlined Authority Code 3675

**[57] Schedule 4, Part 1, entry for Ustekinumab**

**(a)** *omit:*

	C3252	P3252	<p>Chronic plaque psoriasis (whole body) — initial treatment 3</p> <p>Commencement of a Biological Treatment Cycle with an initial PBS-subsidised course of ustekinumab for continuing treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who:</p> <p>(a) have a documented history of severe chronic plaque psoriasis and were receiving treatment with ustekinumab prior to 26 November 2009; and</p> <p>(b) had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with ustekinumab; and</p> <p>(c) have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment of psoriasis affecting the whole body; and</p> <p>(d) have demonstrated a response as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with ustekinumab of psoriasis affecting the whole body; and</p> <p>where biological agent means adalimumab, etanercept, infliximab or ustekinumab; and where a Biological Treatment Cycle is a period of treatment with successive biological agents which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and where the following conditions apply:</p> <p>the application for authorisation is made in writing and includes a completed copy of the</p>	Compliance with Written Authority Required procedures
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			<p>appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition at baseline (prior to initiation of ustekinumab therapy) and the most recent PASI assessment; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and</p> <p>(iii) the signed patient and prescriber acknowledgements;</p> <p>the most recent PASI assessment is no more than 1 month old at the time of application;</p> <p>the course of treatment is limited to a maximum of 24 weeks of treatment;</p> <p>patients are eligible for PBS-subsidised treatment under the above criteria once only</p>	
			<p>Continuation of a course of initial PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis and were receiving non-PBS-subsidised treatment with ustekinumab prior to 26 November 2009, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial PBS-subsidised treatment with ustekinumab for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total</p>	<p>Compliance with Written or Telephone Authority Required procedures</p>

**(b)** *omit:*

	C3254	P3254	<p>Chronic plaque psoriasis (face, hand, foot) — initial treatment 3</p> <p>Commencement of a Biological Treatment Cycle with an initial PBS-subsidised course of ustekinumab for continuing treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over:</p> <p>(a) who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, and were receiving treatment with ustekinumab prior to 26 November 2009; and</p> <p>(b) whose disease, prior to treatment with ustekinumab, was classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot, where either at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe, or the skin area affected was 30% or more of the face, palm of a hand or sole of a foot; and</p> <p>(c) who have signed a patient and prescriber acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment with a biological agent will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment of psoriasis affecting the face, hand or foot; and</p> <p>(d) who have demonstrated a response as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with ustekinumab of psoriasis affecting the face, hand or foot; and</p> <p>where biological agent means adalimumab, etanercept, infliximab or ustekinumab; and</p> <p>where a Biological Treatment Cycle is a period of treatment with successive biological agents</p>	<p>Compliance with Written Authority Required procedures</p>
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		<p>which commences when an eligible patient (one who has not received PBS-subsidised treatment with a biological agent for chronic plaque psoriasis in at least the previous 5 years) receives an initial course of PBS-subsidised therapy with 1 biological agent, and which continues until the patient has tried, and either failed or ceased to respond to, PBS-subsidised treatment with 3 biological agents, at which point the patient is no longer eligible for treatment and the period of treatment ceases; and</p> <p>where the following conditions apply:</p> <p>the application for authorisation is made in writing and includes a completed copy of the appropriate Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of ustekinumab therapy) and the most recent PASI assessment; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy (dosage where applicable, date of commencement and duration of therapy); and</p> <p>(iii) the signed patient and prescriber acknowledgements;</p> <p>the most recent PASI assessment is no more than 1 month old at the time of application;</p> <p>the PASI assessment is performed on the same affected body area as assessed at baseline or prior to initiation of ustekinumab treatment;</p> <p>the course of treatment is limited to a maximum of 24 weeks of treatment;</p> <p>patients are eligible for PBS-subsidised treatment under the above criteria once only</p>	
		<p>Continuation of a course of initial PBS-subsidised treatment as systemic monotherapy (other than methotrexate) by a dermatologist for adults 18 years and over who have a documented history of severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot and were receiving non-PBS-subsidised treatment with ustekinumab prior to 26 November 2009, and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial PBS-subsidised treatment with ustekinumab for a period of less than 24 weeks, and where approval of the application would enable the patient to complete a course of 24 weeks of treatment in total</p>	<p>Compliance with Written or Telephone Authority Required procedures</p>

**1Note**

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>.