PB 26 of 2015

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2015 (No. 3)

National Health Act 1953

I, FELICITY McNEILL, First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health, delegate of the Minister for Health, make this Instrument under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 23 March 2015

FELICITY McNEILL
First Assistant Secretary
Pharmaceutical Benefits Division
Department of Health

1 Name of Instrument

(1) This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2015 (No. 3)*.

(2) This Instrument may also be cited as PB 26 of 2015.

2 Commencement

This Instrument commences on 1 April 2015.

3 Amendment of *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012)

Schedule 1 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012).

Schedule 1 Amendments

[1] Section 4

insert after the definition of ***"electronic communication"****:*

electronic prescription has the meaning given by the Regulations;

[2] Section 4

insert after the definition of ***"palliative care patient"****:*

paper-based prescription has the meaning given by the Regulations;

[3] Section 4

insert after the definition of ***"Regulations"****:*

residential care service has the meaning given by the Regulations;

[4] After subsection 11(2)

insert:

(3) In all circumstances mentioned in Part 1 of Schedule 4 for a circumstances code mentioned in Schedule 1 for the pharmaceutical benefit, except those which include a Streamlined Authority Code, a medication chart prescription for a person receiving treatment in a residential care service may not be authorised under the authority required procedures in sections 11 to 15.

[5] Subsection 12(1)

substitute:

(1) A prescription is submitted in accordance with this subsection if:

(a) the authorised prescriber submits to the Chief Executive Medicare:

(i) the prescription itself; or

(ii) for a medication chart prescription that is not an electronic prescription — the medication chart by which the prescription was written, or a copy of so much of that chart as would indicate that subregulation 19AA(2) of the Regulations has been complied with; or

(b) the authorised prescriber submits details of the prescription by telephone to the Chief Executive Medicare; or

(c) the authorised prescriber submits the prescription in accordance with the instructions in an emergency telephone message provided to the authorised prescriber by the Chief Executive Medicare; or

(d) the authorised prescriber submits details of the prescription to the Chief Executive Medicare, by means of electronic communication of a kind approved in writing by the Chief Executive Medicare.

[6] Subsection 13(1)

substitute:

(1) A paper-based prescription (other than a prescription submitted in accordance with paragraph 12(1)(b), (c) or (d)) may be authorised by the Chief Executive Medicare signing his or her authorisation on the prescription, and:

(a) if the Chief Executive Medicare requires the authorised prescriber to alter the prescription — returning it to the authorised prescriber for alteration before the authorised prescriber gives it to the person in respect of whom it was prepared; or

(b) by returning it to the authorised prescriber; or

(c) if requested by the authorised prescriber — sending it to the person in respect of whom it was prepared.

[7] After subsection 13(1)

insert:

(1A) A medication chart prescription (other than an electronic prescription, or a prescription submitted in accordance with paragraphs 12(1)(b), (c) or (d)) may be authorised by the Chief Executive Medicare signing his or her authorisation on the medication chart prescription, or a copy of the medication chart prescription, and:

(a) if the Chief Executive Medicare requires the authorised prescriber to alter the prescription— indicating this on the medication chart prescription or copy; and

(b) returning the medication chart or copy to the authorised prescriber for alteration.

(1B) An electronic prescription (other than a prescription submitted in accordance with paragraphs 12(1)(b), (c) or (d)) may be authorised by the Chief Executive Medicare writing his or her authorisation on the electronic prescription, and:

(a) if the Chief Executive Medicare requires the authorised prescriber to alter the prescription— by returning it, including by means of an electronic communication, to the authorised prescriber for alteration; or

(b) by returning it, including by means of electronic communication to the authorised prescriber; or

(c) if requested by the authorised prescriber — sending it to the person in respect of whom it was prepared.

[8] Paragraph 13(4)(a)

omit: given by the CEO to the prescription

substitute: that has been allotted to the authorised prescription

[9] Subparagraph 13(4)(b)(ii)

insert after "copy of the prescription": showing the number marked in accordance with subparagraph (i)

[10] Subsection 14(2)

omit: authorised prescriber has:

substitute: authorised prescriber has written the Streamlined Authority Code on the prescription.

[11] Omit paragraphs 14(2)(a) and 14(2)(b)

[12] **Schedule 1, entry for Adalimumab in all forms**

omit from the column headed "Authorised Prescriber" (wherever occurring): **See Note 1**

[13] **Schedule 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C3486**

(b) *omit from the column headed "Circumstances":* **C3749 C3750**

(c) *insert in numerical order":* **C4826 C4840 C4845 C4851 C4864**

[14] **Schedule 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C3486**

(b) *omit from the column headed "Circumstances":* **C3749 C3750**

(c) *insert in numerical order":* **C4826 C4840 C4845 C4851 C4864**

(d) *omit from the column headed "Purposes":* **P3486 P3749**

(e) *insert in numerical order":* **P4826 P4840 P4851**

[15] **Schedule 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 4]***

(a) *omit from the column headed "Circumstances":* **C3486**

(b) *omit from the column headed "Circumstances":* **C3749 C3750**

(c) *insert in numerical order":* **C4826 C4840 C4845 C4851 C4864**

[16] **Schedule 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C3486**

(b) *omit from the column headed "Circumstances":* **C3749 C3750**

(c) *insert in numerical order":* **C4826 C4840 C4845 C4851 C4864**

(d) *omit from the column headed "Purposes":* **P3750**

(e) *insert in numerical order":* **P4845 P4864**

[17] **Schedule 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C3486**

(b) *omit from the column headed "Circumstances":* **C3749 C3750**

(c) *insert in numerical order":* **C4826 C4840 C4845 C4851 C4864**

[18] **Schedule 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C3486**

(b) *omit from the column headed "Circumstances":* **C3749 C3750**

(c) *insert in numerical order":* **C4826 C4840 C4845 C4851 C4864**

(d) *omit from the column headed "Purposes":* **P3486 P3749**

(e) *insert in numerical order":* **P4826 P4840 P4851**

[19] **Schedule 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 4]***

(a) *omit from the column headed "Circumstances":* **C3486**

(b) *omit from the column headed "Circumstances":* **C3749 C3750**

(c) *insert in numerical order":* **C4826 C4840 C4845 C4851 C4864**

[20] Schedule 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C3486**

(b) *omit from the column headed "Circumstances":* **C3749 C3750**

(c) *insert in numerical order":* **C4826 C4840 C4845 C4851 C4864**

(d) *omit from the column headed "Purposes":* **P3750**

(e) *insert in numerical order":* **P4845 P4864**

[21] Schedule 1, after entry for Albendazole in the form Tablet 400 mg

insert:

Alemtuzumab	Solution concentrate for I.V. infusion 12 mg in 1.2 mL	Injection	Lemtrada	GZ	MP	C4829 C4834 C4838 C4850	P4829 P4850	3	0	1	D(100)
					MP	C4829 C4834 C4838 C4850	P4834 P4838	5	0	1	D(100)

[22] Schedule 1, entry for Alendronic acid with colecalciferol in the form Tablet 70 mg (as alendronate sodium) with 70 micrograms colecalciferol

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

Alendronate D3 70 mg/70 microgram	UA	MP NP	C4070 C4087 C4110		4	5	4	

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

APO-Alendronate Plus D3 70 mg/70 mcg	TX	MP NP	C4070 C4087 C4110		4	5	4	

[23] Schedule 1, entry for Alendronic acid with colecalciferol in the form Tablet 70 mg (as alendronate sodium) with 140 micrograms colecalciferol

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

Alendronate D3 70 mg/140 microgram	UA	MP NP	C4122 C4123 C4133		4	5	4	

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

APO-Alendronate Plus D3 70 mg/140 mcg	TX	MP NP	C4122 C4123 C4133		4	5	4	

[24] Schedule 1, entry for Alendronic acid with colecalciferol and calcium

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

Alendronate Plus D3 and Calcium Sandoz	SZ	MP NP	C4122 C4123 C4133	1	5	1

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

Alendronate Plus D3 Calcium Actavis	UA	MP NP	C4122 C4123 C4133	1	5	1

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

ReddyMax Plus D-Cal	RZ	MP NP	C4122 C4123 C4133	1	5	1

[25] Schedule 1, entry for Allopurinol in the form Tablet 100 mg

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

APO-Allopurinol	TX	MP NP		200	2	200

[26] Schedule 1, entry for Allopurinol in the form Tablet 300 mg

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

APO-Allopurinol	TX	MP NP		60	2	60

[27] Schedule 1, entry for Amiodarone in the form Tablet containing amiodarone hydrochloride 200 mg

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

Amiodarone Actavis	GN	MP NP	C1350	30	5	30

[28] Schedule 1, entry for Amitriptyline in the form Tablet containing amitriptyline hydrochloride 10 mg

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

APO-Amitriptyline 10	TX	MP NP		50	2	50

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

Chem mart Amitriptyline	CH	MP NP		50	2	50

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

Terry White Chemists Amitriptyline	TW	MP NP		50	2	50

[29] Schedule 1, entry for Amitriptyline in the form Tablet containing amitriptyline hydrochloride 25 mg

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

	APO-Amitriptyline 25	TX	MP NP	50	2	50	

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

	Chem mart Amitriptyline	CH	MP NP	50	2	50	

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

	Terry White Chemists Amitriptyline	TW	MP NP	50	2	50	

[30] Schedule 1, entry for Amitriptyline in the form Tablet containing amitriptyline hydrochloride 50 mg

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

	APO-Amitriptyline 50	TX	MP NP	50	2	50	

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

	Chem mart Amitriptyline	CH	MP NP	50	2	50	

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

	Terry White Chemists Amitriptyline	TW	MP NP	50	2	50	

[31] Schedule 1, entry for Amlodipine in each of the forms: Tablet 5 mg (as besylate); and Tablet 10 mg (as besylate)

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

	Amlodipine AN	EA	MP NP	30	5	30	

[32] Schedule 1, entry for Amoxycillin with Clavulanic Acid in the form Tablet containing 500 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)

omit from the column headed "Brand" (twice occurring): **Amoxiclav AN 500/125** *substitute:* **Amoxyclav AN 500/125**

[33] Schedule 1, entry for Amoxycillin with Clavulanic Acid in the form Tablet containing 875 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)

omit from the column headed "Brand" (twice occurring): **Amoxiclav AN 875/125** *substitute:* **Amoxyclav AN 875/125**

[34] **Schedule 1, entry for Amoxycillin with Clavulanic Acid in the form Powder for oral suspension containing 125 mg amoxycillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 75 mL *[Maximum Quantity: 1; Number of Repeats 0]***

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

		APO-Amoxycillin and Clavulanic Acid 125/31.25	TX	PDP	C1836 C1837	1	0	1		

[35] **Schedule 1, entry for Amoxycillin with Clavulanic Acid in the form Powder for oral suspension containing 125 mg amoxycillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 75 mL *[Maximum Quantity: 1; Number of Repeats 1]***

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

		APO-Amoxycillin and Clavulanic Acid 125/31.25	TX	MP NP	C1836 C1837	1	1	1		

[36] **Schedule 1, entry for Amoxycillin with Clavulanic Acid in the form Powder for oral suspension containing 400 mg amoxycillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 60 mL *[Maximum Quantity: 1; Number of Repeats 0]***

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

		APO-Amoxycillin and Clavulanic Acid 400/57	TX	PDP	C1836 C1837	1	0	1		

[37] **Schedule 1, entry for Amoxycillin with Clavulanic Acid in the form Powder for oral suspension containing 400 mg amoxycillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 60 mL *[Maximum Quantity: 1; Number of Repeats 1]***

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

		APO-Amoxycillin and Clavulanic Acid 400/57	TX	MP NP	C1836 C1837	1	1	1		

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

insert as first item in the columns in the order indicated:

	Injection containing apomorphine hydrochloride 10 mg in 1 mL	Injection	Apomine	HH	MP	C4833 C4860	360	5	5	D(100)

[39] **Schedule 1, entry for Apomorphine in the form Injection containing apomorphine hydrochloride 20 mg in 2 mL**

(a) *omit from the column headed "Authorised Prescriber":* **See Note 1**

(b) *omit from the column headed "Circumstances":* **C1256 C3314** *substitute* **C4833 C4860**

[40] **Schedule 1, entry for Apomorphine in the form Injection containing apomorphine hydrochloride 50 mg in 5 mL**

(a) *omit from the column headed "Authorised Prescriber":* **See Note 1**

(b) *omit from the column headed "Circumstances":* **C1256 C3314** *substitute* **C4833 C4860**

[41] Schedule 1, entry for Apomorphine in the form Solution for subcutaneous infusion containing apomorphine hydrochloride 50 mg in 10 mL pre-filled syringe

(a) *omit from the column headed "Authorised Prescriber":* **See Note 1**

(b) *omit from the column headed "Circumstances":* **C1256 C3314** *substitute* **C4833 C4860**

[42] Schedule 1, entry for Atorvastatin in the form Tablet 10 mg (as calcium) ***[Maximum Quantity: 30; Number of Repeats 5]***

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

Blooms the Chemist Atorvastatin	IB	MP	C1540 C3047	P1540	30	5	30
		NP	C1540		30	5	30

[43] Schedule 1, entry for Atorvastatin in the form Tablet 10 mg (as calcium) ***[Maximum Quantity: 30; Number of Repeats 11]***

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

Blooms the Chemist Atorvastatin	IB	MP	C1540 C3047	P3047	30	11	30

[44] Schedule 1, entry for Baclofen in the form Tablet 25 mg

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

Terry White Chemists Baclofen	TW	MP NP			100	5	100

[45] Schedule 1, entry for Captopril in each of the forms: Tablet 12.5 mg; Tablet 25 mg; and Tablet 50 mg

omit:

APO-Captopril	TX	MP NP			90	5	90

[46] Schedule 1, entry for Certolizumab pegol

insert in numerical order in the column headed "Circumstances": **C4830 C4831 C4839 C4842 C4843 C4853 C4863**

[47] Schedule 1, entry for Citalopram in the form Tablet 20 mg (as hydrobromide)

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

Citalopram Actavis	VN	MP NP	C1211		28	5	28

[48] Schedule 1, entry for Cyclophosphamide in the form Tablet 50 mg

omit from the column headed "Responsible Person": **PF** *substitute:* **ZX**

[49] Schedule 1, entry for Dapagliflozin

omit from the column headed "Circumstances": **C4736** *substitute:* **C4825 C4844**

[50] Schedule 1, entry for Desvenlafaxine in the form Tablet (extended release) 50 mg (as succinate)

omit from the column headed "Circumstances": **C1211** *substitute:* **C4855**

[51] Schedule 1, after entry for Desvenlafaxine in the form Tablet (extended release) 50 mg (as succinate)

insert in the columns in the order indicated:

	Tablet (modified release) 50 mg	Oral	Desfax	AF	MP NP	C4855		28	5	28
			Desvenlafaxine Actavis	GN	MP NP	C4855		28	5	28
	Tablet (modified release) 50 mg (as benzoate)	Oral	Desvenlafaxine GH XR	GQ	MP NP	C4855		28	5	28

[52] Schedule 1, entry for Desvenlafaxine in the form Tablet (extended release) 100 mg (as succinate)

omit from the column headed "Circumstances": **C1211** *substitute:* **C4855**

[53] Schedule 1, after entry for Desvenlafaxine in the form Tablet (extended release) 100 mg (as succinate)

insert in the columns in the order indicated:

	Tablet (modified release) 100 mg	Oral	Desfax	AF	MP NP	C4855		28	5	28
			Desvenlafaxine Actavis	GN	MP NP	C4855		28	5	28
	Tablet (modified release) 100 mg (as benzoate)	Oral	Desvenlafaxine GH XR	GQ	MP NP	C4855		28	5	28

[54] Schedule 1, entry for Diazepam in the form Tablet 5 mg

(a) *omit:*

			Diazepam-GA	GN	MP NP PDP			50	0	50
					MP NP		P3656	50 CN3656	0	50

(b) *omit:*

			Diazepam-GA	GN	MP NP		P3655	50 CN3655	3 CN3655	50

[55] Schedule 1, after entry for Diphtheria and tetanus vaccine, adsorbed, diluted for adult use in the form Injection 0.5 mL in pre-filled syringe

insert in the columns in the order indicated:

	Injection 0.5 mL	Injection	MassBiologics tetanus and diphtheria toxoids adsorbed	CS	MP NP			10	0	10	PB(MP) PB(NP)

[56] Schedule 1, 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, and in alphabetical order for the column headed "Brand":

			Dotax	RZ	MP		See Note 3	See Note 3	1	D(100)

[57] Schedule 1, entry for Docetaxel in the form Solution concentrate for I.V. infusion 20 mg in 2 mL

omit:

			Docetaxel Sandoz	SZ	MP		See Note 3	See Note 3	1	D(100)

[58] Schedule 1, 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, and in alphabetical order for the column headed "Brand":

			Dotax	RZ	MP		See Note 3	See Note 3	1	D(100)

[59] Schedule 1, after entry for Dolutegravir

insert:

Dolutegravir with abacavir and lamivudine	Tablet containing dolutegravir 50 mg with abacavir 600 mg and lamivudine 300 mg	Oral	Triumeq	VI	MP	C4472 C4480 C4495 C4523	60	5	30	D(100)

[60] Schedule 1, entry for Dorzolamide

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

			Trusamide	QA	MP AO		1	5	1	

[61] Schedule 1, entry for Doxorubicin in each of the forms: Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 10 mg in 5 mL single dose vial; and Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 50 mg in 25 mL single dose vial

omit:

			Doxorubicin Ebewe	SZ	MP		See Note 3	See Note 3	1	D(100)

[62] Schedule 1, entry for Doxorubicin in the form Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 200 mg in 100 mL single dose vial

omit:

			Doxorubicin Ebewe	SZ	MP		See Note 3	See Note 3	1	D(100)

[63] Schedule 1, entry for Empagliflozin in each of the forms: Tablet 10 mg; and Tablet 25 mg

omit from the column headed "Circumstances": **C4770** *substitute:* **C4848**

[64] **Schedule 1, entry for Epirubicin in each of the forms: Solution for injection containing epirubicin hydrochloride 10 mg in 5 mL; Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL; Solution for injection containing epirubicin hydrochloride 100 mg in 50 mL; and Solution for injection containing epirubicin hydrochloride 200 mg in 100 mL**

omit:

	Epirubicin Ebewe	SZ	MP		See Note 3	See Note 3	1	D(100)

[65] **Schedule 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)**

(a) *omit:*

	Esomeprazole Actavis	GN	MP NP	C1337 C1629 C2273 C3429 P2273		30	1	30

(b) *omit:*

	Esomeprazole Actavis	GN	MP NP	C1337 C1629 C2273 C3429	P1337 P1629 P3429	30	5	30

[66] **Schedule 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)**

(a) *omit:*

	Esomeprazole Actavis	GN	MP NP	C1337 C1628 C3429	P1628	30	1	30

(b) *omit:*

	Esomeprazole Actavis	GN	MP NP	C1337 C1628 C3429	P1337 P3429	30	5	30

[67] **Schedule 1, entry for Etanercept in all forms**

omit from the column headed "Authorised Prescriber" (wherever occurring): **See Note 1**

[68] **Schedule 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 *[Maximum Quantity: 1; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C3489 C3776 C3777**

(b) *insert in numerical order:* **C4826 C4840 C4845 C4851 C4864**

(c) *omit from the column headed "Purposes":* **P3489 P3776**

(d) *insert in numerical order:* **P4826 P4840 P4851**

[69] **Schedule 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 *[Maximum Quantity: 1; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C3489 C3776 C3777**

(b) *insert in numerical order:* **C4826 C4840 C4845 C4851 C4864**

(c) *omit from the column headed "Purposes":* **P3777**

(d) *insert in numerical order:* **P4845 P4864**

[70] **Schedule 1, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 *[Maximum Quantity: 1; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C3489 C3776 C3777**
(b) *insert in numerical order:* **C4826 C4840 C4845 C4851 C4864**
(c) *omit from the column headed "Purposes":* **P3489 P3776**
(d) *insert in numerical order:* **P4826 P4840 P4851**

[71] **Schedule 1, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 *[Maximum Quantity: 1; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C3489 C3776 C3777**
(b) *insert in numerical order:* **C4826 C4840 C4845 C4851 C4864**
(c) *omit from the column headed "Purposes":* **P3777**
(d) *insert in numerical order:* **P4845 P4864**

[72] **Schedule 1, entry for Etanercept in the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL *[Maximum Quantity: 2; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C3489 C3776 C3777**
(b) *insert in numerical order:* **C4826 C4840 C4845 C4851 C4864**
(c) *omit from the column headed "Purposes":* **P3489 P3776**
(d) *insert in numerical order:* **P4826 P4840 P4851**

[73] **Schedule 1, entry for Etanercept in the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL *[Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C3489 C3776 C3777**
(b) *insert in numerical order:* **C4826 C4840 C4845 C4851 C4864**
(c) *omit from the column headed "Purposes":* **P3777**
(d) *insert in numerical order:* **P4845 P4864**

[74] **Schedule 1, entry for Everolimus in the form Tablet 5 mg *[Maximum Quantity: 30; Number of Repeats: 2]***

(a) *insert in numerical order in the column headed "Circumstances":* **C4837 C4861**
(b) *insert in numerical order in the column headed "Purposes":* **P4861**

[75] **Schedule 1, entry for Everolimus in the form Tablet 5 mg *[Maximum Quantity: 30; Number of Repeats: 5]***

(a) *insert in numerical order in the column headed "Circumstances":* **C4837 C4861**
(b) *insert in numerical order in the column headed "Purposes":* **P4837**

[76] **Schedule 1, entry for Everolimus in the form Tablet 10 mg *[Maximum Quantity: 30; Number of Repeats: 2]***

(a) *insert in numerical order in the column headed "Circumstances":* **C4837 C4861**
(b) *insert in numerical order in the column headed "Purposes":* **P4861**

[77] **Schedule 1, entry for Everolimus in the form Tablet 10 mg *[Maximum Quantity: 30; Number of Repeats 5]***

(a) *omit from the column headed "Circumstances":* **C4557**

(b) *insert in numerical order:* **C4812 C4837 C4861**

(c) *omit from the column headed "Purposes":* **P4557**

(d) *insert in numerical order:* **P4812 P4837**

[78] 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": **C4392 C4405** *substitute:* **C4856 C4857**

[79] Schedule 1, entry for Fluorouracil in the form Injection 500 mg in 10 mL

omit:

	Fluorouracil Ebewe	SZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	5	D(100)

[80] Schedule 1, entry for Folinic acid in the form Injection containing calcium folinate equivalent to 50 mg folinic acid in 5 mL

omit:

	Calcium Folinate Ebewe	SZ	MP See Note 1			10	2	5	

[81] Schedule 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 3]*

(a) *omit from the column headed "Circumstances":* **C3495 C3497 C3784 C3785**

(b) *insert in numerical order:* **C4826 C4840 C4845 C4851 C4864**

(c) *omit from the column headed "Purposes":* **P3495 P3784**

(d) *insert in numerical order:* **P4826 P4840 P4851**

[82] Schedule 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C3495 C3497 C3784 C3785**

(b) *insert in numerical order:* **C4826 C4840 C4845 C4851 C4864**

(c) *omit from the column headed "Purposes":* **P3497 P3785**

(d) *insert in numerical order:* **P4845 P4864**

[83] Schedule 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 3]*

(a) *omit from the column headed "Circumstances":* **C3495 C3497 C3784 C3785**

(b) *insert in numerical order:* **C4826 C4840 C4845 C4851 C4864**

(c) *omit from the column headed "Purposes":* **P3495 P3784**

(d) *insert in numerical order:* **P4826 P4840 P4851**

[84] Schedule 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C3495 C3497 C3784 C3785**

(b) *insert in numerical order:* **C4826 C4840 C4845 C4851 C4864**

(c) *omit from the column headed "Purposes":* **P3497 P3785**

(d) *insert in numerical order:* **P4845 P4864**

[85] Schedule 1, after entry for Imiquimod in the form Cream 50 mg per g, 250 mg single use sachets, 12 *[Brand: APO-Imiquimod]*

insert in the columns in the order indicated:

IncobotulinumtoxinA	Lyophilised powder for injection 100 units	Injection	Xeomin	EZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[86] Schedule 1, entry for Iron Polymaltose Complex

substitute:

Iron Polymaltose Complex	Injection 100 mg (iron) in 2 mL	Injection	Ferrosig	SI	MP NP			5	0	5
					MP NP		P4302	5 CN4302	5 CN4302	5
			Ferrum H	AS	MP NP			5	0	5
					MP NP		P4302	5 CN4302	5 CN4302	5

[87] Schedule 1, entry for Iron Sucrose

substitute:

Iron sucrose	Concentrate for solution for infusion 2.7 g (equivalent to 100 mg iron (III)) in 5 mL	Injection	Venofer	AS	MP NP			5	0	5
					MP NP		P4302	5 CN4302	5 CN4302	5

[88] Schedule 1, entry for Lanthanum in the form Tablet, chewable, 500 mg (as carbonate hydrate) *[Maximum Quantity: 90; Number of Repeats: 5]*

omit from the column headed "Circumstances": **C3546 C3547** *substitute:* **C4827**

[89] Schedule 1, entry for Lanthanum in the form Tablet, chewable, 500 mg (as carbonate hydrate*) [Maximum Quantity: 180; Number of Repeats: 5]*

(a) *omit from the column headed "Authorised Prescriber":* **See Note 1**

(b) *omit from the column headed "Circumstances":* **C3103 C3104 C3390 C3391** *substitute:* **C4832 C4847**

[90] Schedule 1, entry for Lanthanum in the form Tablet, chewable, 750 mg (as carbonate hydrate) *[Maximum Quantity: 90; Number of Repeats: 5]*

omit from the column headed "Circumstances": **C3546 C3547** *substitute:* **C4827**

[91] Schedule 1, entry for Lanthanum in the form Tablet, chewable, 750 mg (as carbonate hydrate) *[Maximum Quantity: 180; Number of Repeats: 5]*

(a) *omit from the column headed "Authorised Prescriber":* **See Note 1**

(b) *omit from the column headed "Circumstances":* **C3103 C3104 C3390 C3391** *substitute:* **C4832 C4847**

[92] Schedule 1, entry for Lanthanum in the form Tablet, chewable, 1000 mg (as carbonate hydrate) *[Maximum Quantity: 90; Number of Repeats: 5]*

omit from the column headed "Circumstances": **C3546 C3547** *substitute:* **C4827**

[93] Schedule 1, entry for Lanthanum in the form Tablet, chewable, 1000 mg (as carbonate hydrate) *[Maximum Quantity: 180; Number of Repeats: 5]*

(a) *omit from the column headed "Authorised Prescriber":* **See Note 1**

(b) *omit from the column headed "Circumstances":* **C3103 C3104 C3390 C3391** *substitute:* **C4832 C4847**

[94] Schedule 1, entry for Macrogol 3350 in the form Sachets containing powder for oral solution 17 g, 30

omit from the column headed "Brand": **MediHealth** *substitute:* **Herron**

[95] Schedule 1, after entry for Mesalazine in the form Sachet containing prolonged release granules, 2 g per sachet

insert in the columns in the order indicated:

	Sachet containing prolonged release granules, 4 g per sachet	Oral	Pentasa	FP	MP NP	C4824	30	5	30	

[96] Schedule 1, entry for Methotrexate in the form Solution concentrate for I.V. infusion 1000 mg in 10 mL vial

omit:

			Methotrexate Ebewe	SZ	MP	See Note 3	See Note 3	See Note 3	1	PB(100)

[97] Schedule 1, omit entry for Mifepristone

[98] Schedule 1, omit entry for Misoprostol

[99] Schedule 1, entry for Morphine in the form Tablet containing morphine sulfate 60 mg (controlled release)

omit from the column headed "Brand": **APOTEX-MORPHINE MR** *substitute:* **MORPHINE MR APOTEX**

[100] Schedule 1, entry for Nicorandil in each of the forms: Tablets 10 mg, 60; and Tablets 20 mg, 60

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

			Ikotab	QA	MP NP		1	5	1	

[101] Schedule 1, after entry for Oestriol in the form Vaginal cream 1 mg per g, 15 g

insert:

Ofatumumab	Solution concentrate for I.V. infusion 100 mg in 5 mL	Injection	Arzerra	GK	MP	C4828	See Note 3	See Note 3	3	D(100)
	Solution concentrate for I.V. infusion 1000 mg in 50 mL	Injection	Arzerra	GK	MP	C4828 C4858	See Note 3	See Note 3	1	D(100)

[102] Schedule 1, entry for Oxaliplatin in the form Powder for I.V. infusion 50 mg

omit:

			Oxaliplatin Ebewe	SZ	MP			See Note 3	See Note 3	1	D(100)

[103] Schedule 1, entry for Oxaliplatin in the form Powder for I.V. infusion 100 mg

omit:

			Oxaliplatin Ebewe	SZ	MP			See Note 3	See Note 3	1	D(100)

[104] Schedule 1, after entry for Oxycodone with naloxone in the form Tablet (controlled release) containing oxycodone hydrochloride 40 mg with naloxone hydrochloride 20 mg

insert:

Oxytocin	Injection 10 I.U. in 1 mL	Injection	Oxytocin Sandoz	SZ	See Note 4	See Note 4	See Note 4	See Note 4	See Note 4	5	D(MP)

[105] Schedule 1, entry for Paclitaxel in the form Solution concentrate for I.V. infusion 100 mg in 16.7 mL

omit:

			Paclitaxel Ebewe	SZ	MP			See Note 3	See Note 3	1	D(100)

[106] Schedule 1, entry for Perindopril in the form Tablet containing perindopril erbumine 2 mg

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

			Blooms the Chemist Perindopril	IB	MP NP			30	5	30	

[107] Schedule 1, entry for Perindopril in the form Tablet containing perindopril erbumine 4 mg

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

			Blooms the Chemist Perindopril	IB	MP NP			30	5	30	

[108] Schedule 1, entry for Perindopril in the form Tablet containing perindopril erbumine 8 mg

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

			Blooms the Chemist Perindopril	IB	MP NP			30	5	30	

[109] Schedule 1, entry for Polyvinyl Alcohol

omit:

Eye drops 30 mg per mL, 15 mL	Application to the eye	Liquifilm Forte	AG	MP	C1362 C3036	P1362	1	5	1
				NP AO	C1362		1	5	1
		PVA Forte	PE	MP	C1362 C3036	P1362	1	5	1
				NP AO	C1362		1	5	1
		Liquifilm Forte	AG	MP	C1362 C3036	P3036	1	11	1
		PVA Forte	PE	MP	C1362 C3036	P3036	1	11	1

[110] Schedule 1, entry for Raloxifene

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

Raloxifene AN	EA	MP NP	C4071		28	5	28

[111] Schedule 1, entry for Ramipril in the form Tablet 10 mg

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

Ramipril Winthrop	WA	MP NP			30	5	30

[112] Schedule 1, entry for Ranitidine in the form Tablet 300 mg (as hydrochloride)

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

Ranitidine GH	GQ	MP NP			30	5	30

[113] Schedule 1, entry for Salcatonin

omit:

Injection 50 I.U. in 1 mL ampoule	Injection	Miacalcic 50	NV	MP NP	C1412 C3256		30	5	5

[114] Schedule 1, entry for Sevelamer in the form Tablet containing sevelamer hydrochloride 800 mg *[Maximum Quantity: 180; Number of Repeats: 5]*

omit from the column headed "Circumstances": **C3548 C3549** *substitute:* **C4827**

[115] Schedule 1, entry for Sevelamer in the form Tablet containing sevelamer hydrochloride 800 mg *[Maximum Quantity: 360; Number of Repeats: 5]*

(a) *omit from the column headed "Authorised Prescriber":* **See Note 1**
(b) *omit from the column headed "Brand":* **Renagel**
(c) *omit from the column headed "Responsible Person":* **GZ**
(d) *omit from the column headed "Circumstances":* **C3103 C3104 C3390 C3391** *substitute:* **C4832 C4847**

[116] Schedule 1, entry for Sildenafil

(a) *omit from the column headed "Authorised Prescriber" (wherever occurring):* **See Note 1**

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

			Sildenafil AN PHT 20	EA	MP	See Note 3	See Note 3	See Note 3	See Note 3	90		D(100)

[117] Schedule 1, entry for Sorafenib

substitute:

Sorafenib	Tablet 200 mg (as tosylate)	Oral	Nexavar	BN	MP	C4230 C4234 C4820 C4841	P4230 P4234 P4841	120	2	60	
						C4230 C4234 C4820 C4841	P4820	120	5	60	

[118] Schedule 1, after entry for Sucralfate

insert:

Sucroferric oxyhydroxide	Tablet, chewable, 2.5 g (equivalent to 500 mg iron)	Oral	Velphoro	FN	MP NP	C4827		90	5	90	
					MP	C4832 C4847		180	5	90	C(100)

[119] Schedule 1, entry for Sumatriptan in the form Tablet 50 mg (as succinate) ***[Maximum Quantity: 4; Number of Repeats 5; Pack Quantity: 2]***

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

			Iptam	AL	MP NP	C4558		4	5	2	

[120] Schedule 1, entry for Sumatriptan in the form Tablet 50 mg (as succinate) ***[Maximum Quantity: 4; Number of Repeats 5; Pack Quantity: 4]***

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

			Iptam	AL	MP NP	C4558		4	5	4	

[121] Schedule 1, entry for Sunitinib in the form Capsule 12.5 mg (as malate) ***[Maximum Quantity: 28; Number of Repeats: 1]***

omit from the column headed "Circumstances": **C4341 C4354** *substitute:* **C4837 C4862**

[122] Schedule 1, entry for Sunitinib in the form Capsule 12.5 mg (as malate) ***[Maximum Quantity: 28; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C4341 C4354** *substitute:* **C4837 C4862**

(b) *omit from the column headed "Purposes":* **P4354** *substitute:* **P4862**

[123] Schedule 1, entry for Sunitinib in the form Capsule 12.5 mg (as malate) ***[Maximum Quantity: 28; Number of Repeats: 3]***

omit from the column headed "Circumstances": **C4341 C4354** *substitute:* **C4837 C4862**

[124] Schedule 1, entry for Sunitinib in the form Capsule 12.5 mg (as malate) ***[Maximum Quantity: 28; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C4341 C4354** *substitute:* **C4837 C4862**

(b) *omit from the column headed "Purposes":* **P4341** *substitute:* **P4837**

[125] **Schedule 1, entry for Sunitinib in the form Capsule 25 mg (as malate)** ***[Maximum Quantity: 28; Number of Repeats: 1]***

omit from the column headed "Circumstances": **C4341 C4354** *substitute:* **C4837 C4862**

[126] **Schedule 1, entry for Sunitinib in the form Capsule 25 mg (as malate)** ***[Maximum Quantity: 28; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C4341 C4354** *substitute:* **C4837 C4862**

(b) *omit from the column headed "Purposes":* **P4354** *substitute:* **P4862**

[127] **Schedule 1, entry for Sunitinib in the form Capsule 25 mg (as malate)** ***[Maximum Quantity: 28; Number of Repeats: 3]***

omit from the column headed "Circumstances": **C4341 C4354** *substitute:* **C4837 C4862**

[128] **Schedule 1, entry for Sunitinib in the form Capsule 25 mg (as malate)** ***[Maximum Quantity: 28; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C4341 C4354** *substitute:* **C4837 C4862**

(b) *omit from the column headed "Purposes":* **P4341** *substitute:* **P4837**

[129] **Schedule 1, entry for Sunitinib in the form Capsule 50 mg (as malate)** ***[Maximum Quantity: 28; Number of Repeats: 1]***

omit from the column headed "Circumstances": **C4341 C4354** *substitute:* **C4837 C4862**

[130] **Schedule 1, entry for Sunitinib in the form Capsule 50 mg (as malate)** ***[Maximum Quantity: 28; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C4341 C4354** *substitute:* **C4837 C4862**

(b) *omit from the column headed "Purposes":* **P4354** *substitute:* **P4862**

[131] **Schedule 1, entry for Sunitinib in the form Capsule 50 mg (as malate)** ***[Maximum Quantity: 28; Number of Repeats: 3]***

omit from the column headed "Circumstances": **C4341 C4354** *substitute:* **C4837 C4862**

[132] **Schedule 1, entry for Sunitinib in the form Capsule 50 mg (as malate)** ***[Maximum Quantity: 28; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C4341 C4354** *substitute:* **C4837 C4862**

(b) *omit from the column headed "Purposes":* **P4341** *substitute:* **P4837**

[133] **Schedule 1, entry for Tacrolimus in all forms**

omit from the column headed "Authorised Prescriber" (wherever occurring): **See Note 1**

[134] **Schedule 1, entry for Tacrolimus in each of the forms: Capsule 0.5 mg; Capsule 1 mg; and Capsule 5 mg**

omit from the column headed "Responsible Person" for the brand "Prograf" (all instances): **JC** *substitute:* **LL**

[135] **Schedule 1, entry for Tacrolimus in the form Capsule 0.5 mg (once daily prolonged release)**

(a) *omit from the column headed "Responsible Person" for the brand "Prograf XL" (first instance):* **JC** *substitute:* **LL**

(b) *omit from the column headed "Brand" (second instance):* **Prograf XL**

(c) *omit from the column headed "Responsible Person" (second instance):* **JC**

[136] **Schedule 1, entry for Tacrolimus in the form Capsule 1 mg (once daily prolonged release)**

(a) *omit from the column headed "Responsible Person" for the brand "Prograf XL" (first instance):* **JC** *substitute:* **LL**

(b) *omit from the column headed "Brand" (second instance):* **Prograf XL**

(c) *omit from the column headed "Responsible Person" (second instance):* **JC**

[137] Schedule 1, entry for Tacrolimus in the form Capsule 5 mg (once daily prolonged release)

(a) *omit from the column headed "Responsible Person" for the brand "Prograf XL" (first instance):* **JC** *substitute:* **LL**

(b) *omit from the column headed "Brand" (second instance):* **Prograf XL**

(c) *omit from the column headed "Responsible Person" (second instance):* **JC**

[138] Schedule 1, entry for Testosterone in each of the forms: Capsule containing testosterone undecanoate 40 mg; Injection containing testosterone enanthate 250 mg in 1 mL; I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL; Transdermal gel 50 mg in 5 g sachet, 30; Transdermal patches 12.2 mg, 60; Transdermal patches 24.3 mg, 30; and Transdermal solution (pump pack) 30 mg per 1.5 mL dose, 60 doses

omit from the column headed "Circumstances": **C4815 C4816 C4817 C4818 C4819** *substitute:* **C4866 C4867 C4868 C4869 C4870**

[139] Schedule 1, entry for Ursodeoxycholic Acid

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

	Ursosan	BZ	MP NP	C1700		200	2	100

[140] Schedule 1, entry for Varenicline in the form Tablet 1 mg (as tartrate) ***[Maximum Quantity: 56; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C4647**

(b) *insert in numerical order:* **C4835**

(c) *omit from the column headed "Purposes":* **P4647**

(d) *substitute:* **P4835**

[141] Schedule 1, entry for Varenicline in the form Tablet 1 mg (as tartrate) ***[Maximum Quantity: 112; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C4647**

(b) *insert in numerical order:* **C4835**

[142] Schedule 3, after details relevant to Responsible Person code EU

insert:

EZ	Merz Australia Pty Ltd	62 151 073 559

[143] Schedule 3, after details relevant to Responsible Person code FM

insert:

FN	Fresenius Medical Care Australia Pty Ltd	80 067 557 877

[144] Schedule 3, after details relevant to Responsible Person code ZP

insert:

ZX	Zenex Pharmaceuticals Pty Ltd	51 603 281 509

[145] Schedule 4, Part 1, entry for Adalimumab

(a) *omit:*

	C3486	P3486		Psoriatic arthritis — initial treatment 1 Initial treatment commencing a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the	Compliance with Written Authority

				management of psoriatic arthritis, of adults who: (1) have severe active psoriatic arthritis; and (2) have received no prior PBS-subsidised treatment with a biological agent for this condition, or, where the patient has previously received PBS-subsidised treatment with a biological agent for this condition, have received no such treatment for a period of 5 years or more starting from the date the last application for PBS-subsidised therapy with a biological agent for this condition was approved; and (3) have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months and to either sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months or leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; and where biological agent means adalimumab, etanercept, golimumab or infliximab; 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 psoriatic arthritis 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: failure to achieve an adequate response to the treatment regimens specified at (3) above is demonstrated by the following: (a) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and (b) either: (i) an active joint count of at least 20 active (swollen and tender) joints; or (ii) at least 4 active joints from the following list of major joints: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); if the requirement to demonstrate an elevated ESR or CRP cannot be met, the authority application includes the reasons why this criterion cannot be satisfied; if treatment with any of the drugs mentioned at (3) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, the authority application includes details of the contraindication; if intolerance to treatment with the regimens specified at (3) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; the authority application is made in writing and includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form and a signed patient acknowledgment; a course of initial treatment commencing a Treatment Cycle is limited to a maximum of 16 weeks of treatment	Required procedures
				Continuation of a course of initial treatment with adalimumab in a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have severe active psoriatic arthritis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total	Compliance with Written or Telephone Authority Required procedures

(b) *omit:*

	C3749	P3749		Psoriatic arthritis — initial treatment 2 Initial treatment, or recommencement of treatment, with adalimumab within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who: (1) have a documented history of severe active psoriatic arthritis; and (2) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle and are eligible to receive further therapy with a biological agent; and (3) have not failed treatment with adalimumab during the current Treatment Cycle; and where biological agent means adalimumab, etanercept, golimumab or infliximab; 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 psoriatic arthritis 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	Compliance with Written Authority Required procedures

				eligible for treatment and the period of treatment ceases; and where the following conditions apply: patients are eligible to receive further therapy with a biological agent within this Treatment Cycle provided they have not already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle; the authority application is made in writing and includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form; where a patient has received PBS-subsidised treatment with adalimumab within this Treatment Cycle and wishes to recommence therapy with this drug within this same cycle, the authority application is accompanied by evidence of a response to the patient's most recent course of PBS-subsidised adalimumab treatment; the response assessment included in the application is provided to the Chief Executive Medicare no later than 4 weeks from the date the course was ceased, and, where the most recent course of PBS-subsidised adalimumab treatment is a 16-week initial treatment course, is made following a minimum of 12 weeks of therapy; a course of initial treatment within an ongoing Treatment Cycle is limited to a maximum of 16 weeks of treatment	
				Continuation of a course of initial treatment, or of a course which recommences treatment, with adalimumab within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have a documented history of severe active psoriatic arthritis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total	Compliance with Written or Telephone Authority Required procedures
	C3750	P3750		Psoriatic arthritis — continuing treatment Continuing treatment with adalimumab within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults: (1) who have a documented history of severe active psoriatic arthritis; and (2) whose most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle was with adalimumab; and (3) who, at the time of application, demonstrate an adequate response to treatment with adalimumab; and where biological agent means adalimumab, etanercept, golimumab or infliximab; 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 psoriatic arthritis 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: an adequate response to treatment with adalimumab is defined as: (a) an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and (b) either of the following: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); the same indices of disease severity used to establish baseline at the commencement of an initial course of treatment are used to determine response to that course, and subsequent courses, of treatment; the authority application is made in writing and includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with adalimumab; the response assessment included in the application is provided to the Chief Executive Medicare no later than 4 weeks from the cessation of the treatment course; if the most recent course of adalimumab therapy is a 16-week initial treatment course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; if the response assessment to a course of treatment is not submitted to the Chief Executive Medicare within the timeframes specified	Compliance with Written Authority Required procedures

				above, the patient will be deemed to have failed that course of treatment; a course of continuing treatment within an ongoing Treatment Cycle is limited to a maximum of 24 weeks of treatment	
				Continuation of a course of continuing treatment with adalimumab within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have a documented history of severe active psoriatic arthritis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for continuing treatment with this drug 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

(c) *insert in numerical order after existing text:*

	C4826	P4826		Severe psoriatic arthritis Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) Patient must have severe active psoriatic arthritis; AND Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction Patient must be an adult Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth) If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement	Compliance with Written Authority Required procedures
	C4840	P4840		Severe psoriatic arthritis Initial treatment – Initial 2 (change or recommencement of treatment)	Compliance with Written Authority Required procedures

				Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction Patient must be an adult Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth)	
	C4845	P4845		Severe psoriatic arthritis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis	Compliance with Written or Telephone Authority Required procedures
	C4851	P4851		Severe psoriatic arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment; AND	Compliance with Written or Telephone Authority Required procedures

				The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis	
	C4864	P4864		Severe psoriatic arthritis Continuing treatment Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle; AND Patient must demonstrate, at the time of application, an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction Patient must be an adult Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth) The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form	Compliance with Written Authority Required procedures

[146] Schedule 4, Part 1, after entry for Albendazole

insert:

Alemtuzumab	C4829	P4829		Multiple sclerosis Continuing Patient must have previously been issued with an authority prescription for this drug; AND Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must not receive more than one PBS-subsidised treatment per year; AND The treatment must be as monotherapy; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy Must be treated by a neurologist	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4829
	C4834	P4834		Multiple sclerosis	Compliance with Written or Telephone

				Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR; The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be as monotherapy; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years; AND Patient must be ambulatory (without assistance or support) Must be treated by a neurologist Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application	Authority Required procedures - Streamlined Authority Code 4834
	C4838	P4838		Multiple sclerosis Initial treatment The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient; AND The treatment must be as monotherapy; AND Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to the multiple sclerosis, in the preceding 2 years; AND Patient must be ambulatory (without assistance or support) Must be treated by a neurologist Where applicable, the date of the magnetic resonance imaging scan must be provided with the authority application	Compliance with Written or Telephone Authority Required procedures
	C4850	P4850		Multiple sclerosis Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must not show continuing progression of disability while on treatment with this drug; AND Patient must not receive more than one PBS-subsidised treatment per year; AND The treatment must be as monotherapy; AND Patient must have demonstrated compliance with, and an ability to tolerate this therapy Must be treated by a neurologist	Compliance with Written and Telephone Authority Required procedures

[147] Schedule 4, Part 1, entry for Apomorphine

substitute:

Apomorphine	C4833			Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4833
	C4860			Parkinson disease Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy	Compliance with Written or Telephone Authority Required procedures

[148] Schedule 4, Part 1, entry for Certolizumab pegol

insert in numerical order after existing text:

	C4830			Severe psoriatic arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 18 to 20 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 18 to 20 weeks treatment; AND The treatment must provide no more than the balance of up to 18 to 20 weeks treatment available under the above restrictions Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis	Compliance with Written or Telephone Authority Required procedures
	C4831			Severe psoriatic arthritis Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) - balance of supply Patient must have received insufficient therapy with this drug under the Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis	Compliance with Written or Telephone Authority Required procedures
	C4839			Severe psoriatic arthritis Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) Patient must have severe active psoriatic arthritis; AND Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction Patient must be an adult Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or	Compliance with Written Authority Required procedures

				(b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth) If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement	
	C4842			Severe psoriatic arthritis Initial treatment – Initial 2 (change or recommencement of treatment) Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction Patient must be an adult Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth)	Compliance with Written Authority Required procedures
	C4843			Severe psoriatic arthritis	Compliance with Written Authority

				Continuing treatment Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle; AND Patient must demonstrate, at the time of application, an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction Patient must be an adult Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth) The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form	Required procedures
	C4853			Severe psoriatic arthritis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis	Compliance with Written or Telephone Authority Required procedures
	C4863			Severe psoriatic arthritis Initial treatment - Initial 3 (initial PBS-subsidised supply for continuing treatment in a patient commenced on non-PBS-subsidised therapy) Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have been receiving treatment with certolizumab pegol for this condition prior to 1 April 2015; AND Patient must be receiving treatment with certolizumab pegol at the time of application; AND Patient must have demonstrated a response to treatment as specified in the criteria for continuing PBS-subsidised treatment with certolizumab pegol; AND Patient must not receive more than 24 weeks of treatment under this restriction Patient must be an adult Must be treated by a rheumatologist; OR	Compliance with Written Authority Required procedures

				Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement A patient may qualify for PBS-subsidised treatment under this restriction once only	

[149] Schedule 4, Part 1, entry for Dapagliflozin

substitute:

Dapagliflozin	C4825			Diabetes mellitus type 2 The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records	Compliance with Authority Required procedures - Streamlined Authority Code 4825
	C4844			Diabetes mellitus type 2 The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug	Compliance with Authority Required procedures - Streamlined Authority Code 4844

[150] Schedule 4, Part 1, entry for Desvenlafaxine

substitute:

Desvenlafaxine	C4855			Major depressive disorders	

[151] Schedule 4, Part 1, after entry for Dolutegravir

insert:

Dolutegravir with abacavir and lamivudine	C4472			Where the patient is receiving treatment at/from a private hospital HIV infection Initial treatment Patient must be antiretroviral treatment naïve; Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more	Compliance with Written or Telephone Authority Required procedures
	C4480			Where the patient is receiving treatment at/from a public hospital HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4480
	C4495			Where the patient is receiving treatment at/from a public hospital HIV infection Initial treatment Patient must be antiretroviral treatment naïve; Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more	Compliance with Written or Telephone Authority Required procedures – Streamlined Authority Code 4495
	C4523			Where the patient is receiving treatment at/from a private hospital HIV infection Continuing treatment Patient must have previously received PBS-subsidised therapy for HIV infection; Patient must be aged 12 years or older; AND Patient must weigh 40 kg or more	Compliance with Written or Telephone Authority Required procedures

[152] Schedule 4, Part 1, entry for Empagliflozin

substitute:

Empagliflozin	C4848			Diabetes mellitus type 2 The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an	Compliance with Authority Required procedures - Streamlined Authority Code 4848

				SGLT2 inhibitor was initiated Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug	

[153] Schedule 4, Part 1, entry for Etanercept

(a) *omit:*

	C3489	P3489		Psoriatic arthritis — initial treatment 1 Initial treatment commencing a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who: (1) have severe active psoriatic arthritis; and (2) have received no prior PBS-subsidised treatment with a biological agent for this condition, or, where the patient has previously received PBS-subsidised treatment with a biological agent for this condition, have received no such treatment for a period of 5 years or more starting from the date the last application for PBS-subsidised therapy with a biological agent for this condition was approved; and (3) have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months and to either sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months or leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; and where biological agent means adalimumab, etanercept, golimumab or infliximab; 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 psoriatic arthritis 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: failure to achieve an adequate response to the treatment regimens specified at (3) above is demonstrated by the following: (a) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and (b) either: (i) an active joint count of at least 20 active (swollen and tender) joints; or (ii) at least 4 active joints from the following list of major joints: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); if the requirement to demonstrate an elevated ESR or CRP cannot be met, the authority application includes the reasons why this criterion cannot be satisfied; if treatment with any of the drugs mentioned at (3) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, the authority application includes details of the contraindication; if intolerance to treatment with the regimens specified at (3) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; the authority application is made in writing and includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form and a signed patient acknowledgment; a course of initial treatment commencing a Treatment Cycle is limited to a maximum of 16 weeks of treatment	Compliance with Written Authority Required procedures
				Continuation of a course of initial treatment with etanercept in a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have severe active psoriatic arthritis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16	Compliance with Written or Telephone Authority Required

				weeks of treatment in total	procedures
	C3776	P3776		Psoriatic arthritis — initial treatment 2 Initial treatment, or recommencement of treatment, with etanercept within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who: (1) have a documented history of severe active psoriatic arthritis; and (2) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle and are eligible to receive further therapy with a biological agent; and (3) have not failed treatment with etanercept during the current Treatment Cycle; and where biological agent means adalimumab, etanercept, golimumab or infliximab; 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 psoriatic arthritis 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: patients are eligible to receive further therapy with a biological agent within this Treatment Cycle provided they have not already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle; the authority application is made in writing and includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form; where a patient has received PBS-subsidised treatment with etanercept within this Treatment Cycle and wishes to recommence therapy with this drug within this same cycle, the authority application is accompanied by evidence of a response to the patient's most recent course of PBS-subsidised etanercept treatment; the response assessment included in the application is provided to the Chief Executive Medicare no later than 4 weeks from the date the course was ceased, and, where the most recent course of PBS-subsidised etanercept treatment is a 16-week initial treatment course, is made following a minimum of 12 weeks of therapy; a course of initial treatment within an ongoing Treatment Cycle is limited to a maximum of 16 weeks of treatment	Compliance with Written Authority Required procedures
				Continuation of a course of initial treatment, or of a course which recommences treatment, with etanercept within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have a documented history of severe active psoriatic arthritis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total	Compliance with Written or Telephone Authority Required procedures
	C3777	P3777		Psoriatic arthritis — continuing treatment Continuing treatment with etanercept within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults: (1) who have a documented history of severe active psoriatic arthritis; and (2) whose most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle was with etanercept; and (3) who, at the time of application, demonstrate an adequate response to treatment with etanercept; and where biological agent means adalimumab, etanercept, golimumab or infliximab; 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 psoriatic arthritis 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: an adequate response to treatment with etanercept is defined as: (a) an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and (b) either of the following: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or	Compliance with Written Authority Required procedures

				(ii) a reduction in the number of the following major joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); the same indices of disease severity used to establish baseline at the commencement of an initial course of treatment are used to determine response to that course, and subsequent courses, of treatment; the authority application is made in writing and includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with etanercept; the response assessment included in the application is provided to the Chief Executive Medicare no later than 4 weeks from the cessation of the treatment course; if the most recent course of etanercept therapy is a 16-week initial treatment course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; if the response assessment to a course of treatment is not submitted to the Chief Executive Medicare within the timeframes specified above, the patient will be deemed to have failed that course of treatment; a course of continuing treatment within an ongoing Treatment Cycle is limited to a maximum of 24 weeks of treatment	
				Continuation of a course of continuing treatment with etanercept within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have a documented history of severe active psoriatic arthritis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for continuing treatment with this drug 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

(b) *insert in numerical order after existing text:*

	C4826	P4826		Severe psoriatic arthritis Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) Patient must have severe active psoriatic arthritis; AND Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction Patient must be an adult Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or	Compliance with Written Authority Required procedures

				(b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth) If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement	
	C4840	P4840		Severe psoriatic arthritis Initial treatment – Initial 2 (change or recommencement of treatment) Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction Patient must be an adult Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth)	Compliance with Written Authority Required procedures
	C4845	P4845		Severe psoriatic arthritis	Compliance with Written or Telephone

				Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis	Authority Required procedures
	C4851	P4851		Severe psoriatic arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis	Compliance with Written or Telephone Authority Required procedures
	C4864	P4864		Severe psoriatic arthritis Continuing treatment Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle; AND Patient must demonstrate, at the time of application, an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction Patient must be an adult Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth) The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form	Compliance with Written Authority Required procedures

[154] Schedule 4, Part 1, entry for Everolimus

insert in numerical order after existing text:

	C4837	P4837		Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must not have disease progression; AND The treatment must be as monotherapy Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug	Compliance with Authority Required procedures
	C4861	P4861		Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Initial treatment Patient must be symptomatic (despite somatostatin analogues); OR Patient must have disease progression; AND The treatment must be as monotherapy Disease progression must be documented in the patient's medical records Patients who have developed progressive disease on sunitinib are not eligible to receive PBS-subsidised everolimus Patients who have developed intolerance to sunitinib of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised everolimus	Compliance with Authority Required procedures

[155] Schedule 4, Part 1, entry for Exenatide

substitute:

Exenatide	C4856			Diabetes mellitus type 2 The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR Patient must not have tolerated a combination of metformin and a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records	Compliance with Authority Required procedures - Streamlined Authority Code 4856
	C4857			Diabetes mellitus type 2 The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR	Compliance with Authority Required procedures - Streamlined Authority Code 4857

				Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records	

[156] Schedule 4, Part 1, entry for Golimumab

(a) *omit:*

	C3495	P3495		Psoriatic arthritis — initial treatment 1 Initial treatment commencing a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who: (1) have severe active psoriatic arthritis; and (2) have received no prior PBS-subsidised treatment with a biological agent for this condition, or, where the patient has previously received PBS-subsidised treatment with a biological agent for this condition, have received no such treatment for a period of 5 years or more starting from the date the last application for PBS-subsidised therapy with a biological agent for this condition was approved; and (3) have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months and to either sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months or leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; and where biological agent means adalimumab, etanercept, golimumab or infliximab; 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 psoriatic arthritis 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: failure to achieve an adequate response to the treatment regimens specified at (3) above is demonstrated by the following: (a) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and (b) either: (i) an active joint count of at least 20 active (swollen and tender) joints; or (ii) at least 4 active joints from the following list of major joints: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); if the requirement to demonstrate an elevated ESR or CRP cannot be met, the authority application includes the reasons why this criterion cannot be satisfied; if treatment with any of the drugs mentioned at (3) above is contraindicated according to the relevant Therapeutic Goods Administration-approved Product Information, the authority application includes details of the contraindication; if intolerance to treatment with the regimens specified at (3) above develops during the relevant period of use and is of a severity necessitating permanent treatment withdrawal, the authority application includes details of the degree of this toxicity; the authority application is made in writing and includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form and a signed patient acknowledgment; a course of initial treatment commencing a Treatment Cycle is limited to a maximum of 16 weeks of treatment	Compliance with Written Authority Required procedures

				Continuation of a course of initial treatment with golimumab in a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have severe active psoriatic arthritis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total	Compliance with Written or Telephone Authority Required procedures
	C3497	P3497		Psoriatic arthritis — initial treatment 3 Commencement of a Biological Treatment Cycle, with an initial PBS-subsidised course of golimumab for continuing treatment, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who: (1) have a documented history of severe active psoriatic arthritis; and (2) were receiving treatment with golimumab prior to 1 March 2010; and (3) have demonstrated a response to golimumab treatment as specified in the criteria for continuing PBS-subsidised treatment with golimumab; and (4) are receiving treatment with golimumab at the time of application; and where biological agent means adalimumab, etanercept, golimumab or infliximab; 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 psoriatic arthritis 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 authority application is made in writing and includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form and a signed patient acknowledgment; 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	Compliance with Written Authority Required procedures
				Continuation of a course of initial PBS-subsidised treatment with golimumab commencing a Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have a documented history of severe active psoriatic arthritis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment with this drug 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
	C3784	P3784		Psoriatic arthritis — initial treatment 2 Initial treatment, or recommencement of treatment, with golimumab within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who: (1) have a documented history of severe active psoriatic arthritis; and (2) have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle and are eligible to receive further therapy with a biological agent; and (3) have not failed treatment with golimumab during the current Treatment Cycle; and where biological agent means adalimumab, etanercept, golimumab or infliximab; 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 psoriatic arthritis 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: patients are eligible to receive further therapy with a biological agent within this Treatment Cycle provided they have not already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle; the authority application is made in writing and includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form; where a patient has received PBS-subsidised treatment with golimumab within this Treatment Cycle and wishes to recommence therapy with this drug within this same cycle, the authority application is accompanied by evidence of a response to the patient's most recent course of PBS-subsidised golimumab treatment; the response assessment included in the application is provided to the Chief Executive Medicare no later than 4 weeks from the date the course was ceased, and, where the most recent course of PBS-subsidised golimumab treatment is a 16-week initial treatment	Compliance with Written Authority Required procedures

				course, is made following a minimum of 12 weeks of therapy; a course of initial treatment within an ongoing Treatment Cycle is limited to a maximum of 16 weeks of treatment	
				Continuation of a course of initial treatment, or of a course which recommences treatment, with golimumab within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have a documented history of severe active psoriatic arthritis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for initial treatment or recommencement of treatment with this drug for a period of less than 16 weeks, and where approval of the application would enable the patient to complete a course of 16 weeks of treatment in total	Compliance with Written or Telephone Authority Required procedures
	C3785	P3785		Psoriatic arthritis — continuing treatment Continuing treatment with golimumab within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults: (1) who have a documented history of severe active psoriatic arthritis; and (2) whose most recent course of PBS-subsidised treatment with a biological agent for this condition in the current Treatment Cycle was with golimumab; and (3) who, at the time of application, demonstrate an adequate response to treatment with golimumab; and where biological agent means adalimumab, etanercept, golimumab or infliximab; 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 psoriatic arthritis 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: an adequate response to treatment with golimumab is defined as: (a) an erythrocyte sedimentation rate no greater than 25 mm per hour or a C-reactive protein level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and (b) either of the following: (i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (ii) a reduction in the number of the following major joints which are active, from at least 4, by at least 50%: — elbow, wrist, knee and/or ankle (assessed as active if swollen and tender); and/or — shoulder and/or hip (assessed as active if there is pain in passive movement and restriction of passive movement, and where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); the same indices of disease severity used to establish baseline at the commencement of an initial course of treatment are used to determine response to that course, and subsequent courses, of treatment; the authority application is made in writing and includes a completed copy of the appropriate Psoriatic Arthritis PBS Authority Application - Supporting Information Form, and a measurement of response to the most recent prior course of therapy with golimumab; the response assessment included in the application is provided to the Chief Executive Medicare no later than 4 weeks from the cessation of the treatment course; if the most recent course of golimumab therapy is a 16-week initial treatment course, the application for continuing treatment is accompanied by an assessment of response to a minimum of 12 weeks of treatment with that course; if the response assessment to a course of treatment is not submitted to the Chief Executive Medicare within the timeframes specified above, the patient will be deemed to have failed that course of treatment; a course of continuing treatment within an ongoing Treatment Cycle is limited to a maximum of 24 weeks of treatment	Compliance with Written Authority Required procedures
				Continuation of a course of continuing treatment with golimumab within an ongoing Biological Treatment Cycle, by a rheumatologist or by a clinical immunologist with expertise in the management of psoriatic arthritis, of adults who have a documented history of severe active psoriatic arthritis and who, qualifying under the criteria specified above, have previously been issued with an authority prescription for continuing treatment with this drug 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

(b) *insert in numerical order after existing text:*

	C4826	P4826		Severe psoriatic arthritis Initial treatment – Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) Patient must have severe active psoriatic arthritis; AND Patient must have received no prior PBS-subsidised treatment with a biological agent for this condition; OR Patient must have received no PBS-subsidised treatment with a biological agent for at least 5 years if they have previously received PBS-subsidised treatment with a biological agent for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction Patient must be an adult Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth) If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form; and (3) a signed patient acknowledgement	Compliance with Written Authority Required procedures
	C4840	P4840		Severe psoriatic arthritis Initial treatment – Initial 2 (change or recommencement of treatment) Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents within this Treatment Cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug during the current Treatment Cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction Patient must be an adult	Compliance with Written Authority Required procedures

				Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form Applications for a patient who has previously received PBS-subsidised treatment with this drug within this Treatment Cycle and who wishes to recommence therapy with this drug within this same Cycle, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug Where the most recent course of PBS-subsidised treatment was approved under either of the initial treatment restrictions (i.e. for patients with no prior PBS-subsidised biological therapy or, under this restriction, for patients who have received previous PBS-subsidised biological therapy), the patient must have been assessed for response following a minimum of 12 weeks of therapy. This assessment must have been submitted no later than 4 weeks from the date that course was ceased Where the most recent course of PBS-subsidised treatment with this drug was approved under the continuing treatment criteria, the patient must have been assessed for response, and the assessment submitted no later than 4 weeks from the date that course was ceased Where a response assessment was not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth)	
	C4845	P4845		Severe psoriatic arthritis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis	Compliance with Written or Telephone Authority Required procedures
	C4851	P4851		Severe psoriatic arthritis Initial treatment - Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) or Initial 2 (change or recommencement of treatment) - balance of supply Patient must have received insufficient therapy with this drug under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis	Compliance with Written or Telephone Authority Required procedures
	C4864	P4864		Severe psoriatic arthritis Continuing treatment Patient must have a documented history of severe active psoriatic arthritis; AND Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological agent for this	Compliance with Written Authority Required procedures

				condition in the current Treatment Cycle; AND Patient must demonstrate, at the time of application, an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction Patient must be an adult Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis For the purposes of this restriction 'biological agent' means adalimumab, certolizumab pegol, etanercept, golimumab or infliximab An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth) The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications All applications for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course Where a response assessment is not submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Psoriatic Arthritis PBS Authority Application - Supporting Information Form	

[157] Schedule 4, Part 1, entry for Iron Polymaltose Complex

insert in the column headed "Conditions Code": **CN4302**

[158] Schedule 4, Part 1, entry for Iron Sucrose

substitute:

Iron sucrose		P4302	CN4302	Iron deficiency anaemia Patient must be undergoing chronic haemodialysis	Compliance with Authority Required procedures - Streamlined Authority Code 4302

[159] Schedule 4, Part 1, entry for Lanthanum

substitute:

Lanthanum	C4827			Hyperphosphataemia Maintenance following initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other phosphate binding agents	Compliance with Authority Required procedures - Streamlined Authority Code 4827

				Patient must be undergoing dialysis for chronic kidney disease	
	C4832			Where the patient is receiving treatment at/from a public hospital Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other phosphate binding agents Patient must be undergoing dialysis for chronic kidney disease	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4832
	C4847			Where the patient is receiving treatment at/from a private hospital Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other phosphate binding agents Patient must be undergoing dialysis for chronic kidney disease	Compliance with Written and Telephone Authority Required procedures

[160] Schedule 4, Part 1, entry for Mesalazine

insert in numerical order in the columns in the order indicated:

	C4824			Ulcerative colitis Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR Patient must be intolerant to sulfasalazine	Compliance with Authority Required procedures - Streamlined Authority Code 4824

[161] Schedule 4, Part 1, omit entry for Mifepristone

[162] Schedule 4, Part 1, omit entry for Misoprostol

[163] Schedule 4, Part 1, after entry for Octreotide

insert:

Ofatumumab	C4828			Chronic lymphocytic leukaemia (CLL) Initial treatment The condition must be CD20 positive chronic lymphocytic leukaemia (CLL); AND The condition must be previously untreated; AND The treatment must be in combination with chlorambucil; AND Patient must be inappropriate for fludarabine based therapy	Compliance with Authority Required procedures - Streamlined Authority Code 4828
	C4858			Chronic lymphocytic leukaemia (CLL) Continuing treatment The condition must be CD20 positive chronic lymphocytic leukaemia (CLL); AND Patient must have previously been issued with an authority prescription for this drug; AND Patient must not have progressive disease; AND Patient must be inappropriate for fludarabine based therapy; AND The treatment must be in combination with chlorambucil	Compliance with Authority Required procedures - Streamlined Authority Code 4858

[164] Schedule 4, Part 1, entry for Sevelamer

substitute:

Sevelamer	C4827			Hyperphosphataemia Maintenance following initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other phosphate binding agents Patient must be undergoing dialysis for chronic kidney disease	Compliance with Authority Required procedures - Streamlined Authority Code 4827
	C4832			Where the patient is receiving treatment at/from a public hospital Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other phosphate binding agents Patient must be undergoing dialysis for chronic kidney disease	Compliance with Written or Telephone Authority Required procedures - Streamlined Authority Code 4832
	C4847			Where the patient is receiving treatment at/from a private hospital Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other phosphate binding agents Patient must be undergoing dialysis for chronic kidney disease	Compliance with Written or Telephone Authority Required procedures

[165] Sorafenib

(a) *insert in numerical order in the column headed "Purposes Code" for Circumstances Code C4230:* **P4230**

(b) *insert in numerical order in the column headed "Purposes Code" for Circumstances Code C4234:* **P4234**

(c) *insert in numerical order after existing text:*

	C4820	P4820		Stage IV clear cell variant renal cell carcinoma (RCC) Continuing treatment beyond 3 months Patient must have previously been issued with an authority prescription for this drug for this condition; AND Patient must have stable or responding disease according to the Response Evaluation Criteria In Solid Tumours (RECIST); AND The treatment must be the sole PBS-subsidised therapy for this condition A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug	Compliance with Authority Required procedures
	C4841	P4841		Stage IV clear cell variant renal cell carcinoma (RCC) Initial treatment Patient must have progressive disease according to the Response Evaluation Criteria In Solid Tumours (RECIST) following first-line treatment with a tyrosine kinase inhibitor; AND Patient must have a WHO performance status of 2 or less; AND The treatment must be the sole PBS-subsidised therapy for this condition	Compliance with Authority Required procedures

				Patients who have developed intolerance to a tyrosine kinase inhibitor of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised treatment with this drug A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug	

[166] Schedule 4, Part 1, after entry for Strontium

insert:

Sucroferric oxyhydroxide	C4827			Hyperphosphataemia Maintenance following initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other phosphate binding agents Patient must be undergoing dialysis for chronic kidney disease	Compliance with Authority Required procedures - Streamlined Authority Code 4827
	C4832			Where the patient is receiving treatment at/from a public hospital Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other phosphate binding agents Patient must be undergoing dialysis for chronic kidney disease	Compliance with Written and Telephone Authority Required procedures - Streamlined Authority Code 4832
	C4847			Where the patient is receiving treatment at/from a private hospital Hyperphosphataemia Initiation and stabilisation The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other phosphate binding agents Patient must be undergoing dialysis for chronic kidney disease	Compliance with Written and Telephone Authority Required procedures

[167] Schedule 4, Part 1, entry for Sunitinib

omit:

	C4341	P4341		Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Continuing treatment Patient must have previously been issued with an authority prescription for sunitinib; Patient must not have progressive disease; The treatment must be as monotherapy	Compliance with Authority Required procedures
	C4354	P4354		Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Initial treatment Patient must be symptomatic (despite somatostatin analogues); OR Patient must have disease progression; The treatment must be as monotherapy Disease progression must be documented in the patient's medical records	Compliance with Authority Required procedures

substitute:

	C4837	P4837		Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Continuing treatment Patient must have previously been issued with an authority prescription for this drug; AND Patient must not have disease progression; AND The treatment must be as monotherapy Patients who have progressive disease with this drug are no longer eligible for PBS-subsidised treatment with this drug	Compliance with Authority Required procedures
	C4862	P4862		Metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET) Initial treatment Patient must be symptomatic (despite somatostatin analogues); OR Patient must have disease progression; AND The treatment must be as monotherapy Disease progression must be documented in the patient's medical records Patients who have developed progressive disease on everolimus are not eligible to receive PBS-subsidised sunitinib for this condition Patients who have developed intolerance to everolimus of a severity necessitating permanent treatment withdrawal are eligible to receive PBS-subsidised sunitinib	Compliance with Authority Required procedures

[168] Schedule 4, Part 1, entry for Testosterone

substitute:

Testosterone	C4866			Androgen deficiency Patient must not have an established pituitary or testicular disorder; AND The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs Patient must be male; AND Patient must be aged 40 years or older Must be treated by a specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists Androgen deficiency is defined as: (i) testosterone level of less than 6 nmol per litre; OR (ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher) Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated The name of the specialist must be included in the authority application	Compliance with Authority Required procedures
	C4867			Micropenis Patient must be male; AND Patient must be under 18 years of age Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists The name of the specialist must be included in the authority application	Compliance with Authority Required procedures
	C4868			Androgen deficiency Patient must have an established pituitary or testicular disorder Patient must be male	Compliance with Authority Required procedures

				Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists The name of the specialist must be included in the authority application	
	C4869			Pubertal induction Patient must be male; AND Patient must be under 18 years of age Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists The name of the specialist must be included in the authority application.	Compliance with Authority Required procedures
	C4870			Constitutional delay of growth or puberty Patient must be male; AND Patient must be under 18 years of age Must be treated by a specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a registered member of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists The name of the specialist must be included in the authority application	Compliance with Authority Required procedures

[169] Schedule 4, Part 1, entry for Varenicline

(a) *omit:*

	C4647	P4647		Nicotine dependence Completion of a short-term (24 weeks) course of treatment The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously been issued with an authority prescription for this drug during this current course of treatment; AND Patient must have ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program	Compliance with Authority Required procedures

(b) *insert in numerical order after existing text:*

	C4835	P4835		Nicotine dependence Completion of a short-term (24 weeks) course of treatment The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously been issued with an authority prescription for this drug during this current course of treatment; AND Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program	Compliance with Authority Required procedures