PB 74 of 2025

National Health (Listing of Pharmaceutical Benefits) Amendment (July Update) Instrument 2025

National Health Act 1953

I, REBECCA RICHARDSON, Assistant Secretary, Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health, Disability and Ageing, delegate of the Minister for Health and Ageing, make this Instrument under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 26 June 2025

REBECCA RICHARDSON
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division

Contents

1. Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (July Update) Instrument 2025*.

(2) This Instrument may also be cited as PB 74 of 2025.

2. Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement Information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 July 2025	1 July 2025

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3. Authority

This instrument is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

4. Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Listing of Pharmaceutical Benefits) Instrument 2024 (PB 26 of 2024)

[1] Schedule 1, Part 1, entries for Abemaciclib in each of the forms: Tablet 50 mg; Tablet 100 mg; and Tablet 150 mg

(a) omit from the column headed "Circumstances": C15186

(b) insert in numerical order in the column headed "Circumstances": C16771

[2] Schedule 1, Part 1, entries for Aciclovir in the form Tablet 200 mg *[Brand: Aciclovir APOTEX]*

(a) omit from the column headed "Purposes": P5936

(b) omit:

Aciclovir	Tablet 200 mg	Oral	Aciclovir APOTEX	TY	MP NP MW	C5942	P5942	90	5	90

[3] Schedule 1, Part 1, entries for Allopurinol in the form Tablet 100 mg

omit:

Allopurinol	Tablet 100 mg	Oral	Allopurinol APOTEX	GX	MP NP			200	2	200
Allopurinol	Tablet 100 mg	Oral	Allopurinol APOTEX	GX	MP NP		P14238	400	2	200

[4] Schedule 1, Part 1, entry for Amifampridine

omit from the column headed "Responsible Person": OJ *substitute:* LD

[5] Schedule 1, Part 1, entries for Amlodipine in the form Tablet 5 mg (as besilate)

omit:

Amlodipine	Tablet 5 mg (as besilate)	Oral	Amlodipine APOTEX	GX	MP NP			30	5	30
Amlodipine	Tablet 5 mg (as besilate)	Oral	Amlodipine APOTEX	GX	MP NP		P14238	60	5	30

[6] Schedule 1, Part 1, entries for Amoxicillin in the form Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL

omit:

Amoxicillin	Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL	Oral	Cilamox	AL	PDP		1	0	1
Amoxicillin	Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL	Oral	Cilamox	AL	MP NP MW		1	1	1

[7] Schedule 1, Part 1, after entry for Aripiprazole in the form Powder for injection 400 mg (as monohydrate) with diluent

insert:

Aripiprazole	Powder for injection 400 mg (as monohydrate) with diluent	Injection	ARIPENA	RA	MP NP	C4246	1	5	1

[8] Schedule 1, Part 1, after entry for Azithromycin in the form Tablet 500 mg (as dihydrate) *[Brand: Zithromax; Maximum Quantity: 2; Number of Repeats: 2]*

insert:

Azithromycin	Tablet 500 mg (as dihydrate) (S19A)	Oral	Azithromycin Tablets, USP 500 mg (Precision Dose, USA)	RQ	MP MW NP	C5718 C5772	P5718 P5772	2	0	3	
Azithromycin	Tablet 500 mg (as dihydrate) (S19A)	Oral	Azithromycin Tablets, USP 500 mg (Precision Dose, USA)	RQ	MP NP	C5637	P5637	2	2	3	

[9] Schedule 1, Part 1, after entry for Belzutifan

insert:

Bendamustine	Powder for injection containing bendamustine hydrochloride 25 mg	Injection	BENDAMUSTINE EUGIA	YG	MP	C7943 C7944 C7972	See Note 3	See Note 3	1	D(100)

[10] Schedule 1, Part 1, after entry for Bendamustine in the form Powder for injection containing bendamustine hydrochloride 25 mg *[Brand: Bendamustine Viatris]*

insert:

Bendamustine	Powder for injection containing bendamustine hydrochloride 100 mg	Injection	BENDAMUSTINE EUGIA	YG	MP	C7943 C7944 C7972		See Note 3	See Note 3	1	D(100)

[11] Schedule 1, Part 1, entries for Bivalirudin

omit:

Bivalirudin	Powder for I.V. injection 250 mg (as trifluoroacetate)	Injection	Bivalirudin APOTEX	TX	MP	C4919		1	0	1	

[12] Schedule 1, Part 1, entries for Bosentan in the form Tablet 62.5 mg (as monohydrate)

omit:

Bosentan	Tablet 62.5 mg (as monohydrate)	Oral	Bosentan Mylan	AF	MP	See Note 3	See Note 3	See Note 3	See Note 3	60	D(100)

[13] Schedule 1, Part 1, entries for Carbamazepine in the form Tablet 200 mg (controlled release)

(a) omit:

Carbamazepine	Tablet 200 mg (controlled release)	Oral	Tegretol CR 200	NV	PDP			200	0	200	

(b) omit:

Carbamazepine	Tablet 200 mg (controlled release)	Oral	Tegretol CR 200	NV	MP NP		P16524	200	2	200	

(c) omit:

Carbamazepine	Tablet 200 mg (controlled release)	Oral	Tegretol CR 200	NV	MP NP		P16493	400	2	200	

[14] Schedule 1, Part 1, entries for Carbamazepine in the form Tablet 400 mg (controlled release)

(a) omit:

Carbamazepine	Tablet 400 mg (controlled release)	Oral	Tegretol CR 400	NV	PDP		200	0	200

(b) omit:

Carbamazepine	Tablet 400 mg (controlled release)	Oral	Tegretol CR 400	NV	MP NP	P16524	200	2	200

(c) omit:

Carbamazepine	Tablet 400 mg (controlled release)	Oral	Tegretol CR 400	NV	MP NP	P16493	400	2	200

[15] Schedule 1, Part 1, entries for Cariprazine

omit from the column headed "Responsible Person" (all instances): CS *substitute (all instances):* IX

[16] Schedule 1, Part 1, entries for Cefaclor in the form Powder for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL

omit:

Cefaclor	Powder for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL	Oral	Aclor 125	MQ	PDP	1	0	1
Cefaclor	Powder for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL	Oral	Aclor 125	MQ	MP	1	1	1

[17] Schedule 1, Part 1, entries for Cefaclor in the form Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL

omit:

Cefaclor	Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL	Oral	Aclor 250	MQ	PDP	1	0	1
Cefaclor	Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL	Oral	Aclor 250	MQ	MP	1	1	1

[18] Schedule 1, Part 1, entries for Cefaclor in the form Tablet (sustained release) 375 mg (as monohydrate)

omit:

Cefaclor	Tablet (sustained release) 375 mg (as monohydrate)	Oral	Karlor CD	MQ	PDP	10	0	10	
Cefaclor	Tablet (sustained release) 375 mg (as monohydrate)	Oral	Karlor CD	MQ	MP	10	1	10	

[19] Schedule 1, Part 1, entry for Clobetasol in the form Shampoo containing clobetasol propionate 500 microgram per mL, 125 mL

omit from the column headed "Form": Shampoo containing clobetasol propionate 500 microgram per mL, 125 mL *substitute:* Shampoo containing clobetasol propionate 500 micrograms per mL, 125 mL

[20] Schedule 1, Part 1, entries for Dexamethasone

omit:

Dexamethasone	Eye drops 1 mg per mL, 5 mL	Application to the eye	Maxidex	NV	AO	1	0	1	
Dexamethasone	Eye drops 1 mg per mL, 5 mL	Application to the eye	Maxidex	NV	MP NP	1	2	1	

[21] Schedule 1, Part 1, entries 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	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 200 mg in 100 mL single dose vial	Injection/intravesical	Adriamycin	PF	MP	See Note 3	See Note 3	1	D(100)

[22] Schedule 1, Part 1, after entry for Doxycycline in the form Tablet 100 mg (as monohydrate) *[Maximum Quantity: 56; Number of Repeats: 2]*

insert:

Drospirenone	Pack containing 24 tablets 4 mg and 4 inert tablets	Oral	Slinda	HB	MP MW NP	4	2	1	

[23] Schedule 1, Part 1, entries for Etanercept

substitute:

Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	PF	MP	C9417 C14068 C14070 C14071 C14154 C14155	See Note 3	See Note 3	See Note 3	1	C(100)
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	PF	MP	C14508 C14509	P14508 P14509	2	1	1	
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	PF	MP	C9064 C9386 C12261 C14488 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14703 C16709 C16710 C16713 C16716 C16717 C16727 C16728 C16737 C16743 C16747 C16748 C16761 C16763 C16764 C16773 C16777 C16779 C16785 C16788	P9064 P9386 P12261 P14488 P14513 P14552 P14553 P14554 P14576 P14577 P14600 P14703 P16709 P16710 P16713 P16716 P16717 P16727 P16728 P16737 P16743 P16747 P16748 P16761 P16763 P16764 P16773 P16777 P16779 P16785 P16788	2	3	1	
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	PF	MP	C8879 C9081 C12123 C14499 C14507 C14715 C16718 C16725 C16750 C16753 C16754 C16765 C16766 C16772 C16774 C16775 C16789 C16792	P8879 P9081 P12123 P14499 P14507 P14715 P16718 P16725 P16750 P16753 P16754 P16765 P16766 P16772 P16774 P16775 P16789 P16792	2	5	1	
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Brenzys	RF	MP	C9064 C14488 C14581 C14582 C14603 C14670 C14671 C14673	P9064 P14488 P14581 P14582 P14603 P14670 P14671 P14673	1	3	1	

						C14703 C16709 C16710 C16713 C16716 C16717 C16737 C16743 C16747 C16748 C16761 C16763 C16764 C16773 C16779 C16785 C16788	P14703 P16709 P16710 P16713 P16716 P16717 P16737 P16743 P16747 P16748 P16761 P16763 P16764 P16773 P16779 P16785 P16788				
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Brenzys	RF	MP	C8879 C9081 C14499 C14507 C14629 C14683 C14701 C14715 C16720 C16725 C16750 C16753 C16754 C16765 C16766 C16772 C16774 C16778 C16789 C16792 C16795	P8879 P9081 P14499 P14507 P14629 P14683 P14701 P14715 P16720 P16725 P16750 P16753 P16754 P16765 P16766 P16772 P16774 P16778 P16789 P16792 P16795	1	5	1	
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Enbrel	PF	MP	C9417 C14068 C14070 C14071 C14154 C14155	See Note 3	See Note 3	See Note 3	1	C(100)
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Enbrel	PF	MP	C14508 C14509	P14508 P14509	1	1	1	
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Enbrel	PF	MP	C9064 C9386 C12261 C14488 C14513 C14552 C14553 C14554 C14576 C14577 C14600 C14703 C16709 C16710 C16713 C16716 C16717 C16727 C16728 C16737 C16743 C16747 C16748 C16761 C16763 C16764 C16773 C16777 C16779 C16785 C16788	P9064 P9386 P12261 P14488 P14513 P14552 P14553 P14554 P14576 P14577 P14600 P14703 P16709 P16710 P16713 P16716 P16717 P16727 P16728 P16737 P16743 P16747 P16748 P16761 P16763 P16764 P16773 P16777 P16779 P16785 P16788	1	3	1	

Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Enbrel	PF	MP	C8879 C9081 C12123 C14499 C14507 C14715 C16718 C16725 C16750 C16753 C16754 C16765 C16766 C16772 C16774 C16775 C16789 C16792	P8879 P9081 P12123 P14499 P14507 P14715 P16718 P16725 P16750 P16753 P16754 P16765 P16766 P16772 P16774 P16775 P16789 P16792	1	5	1	
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Nepexto	GQ	MP	C9417 C14068 C14070 C14071 C14154 C14155	See Note 3	See Note 3	See Note 3	1	C(100)
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Nepexto	GQ	MP	C14508 C14509	P14508 P14509	1	1	1	
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Nepexto	GQ	MP	C9064 C9386 C12261 C14488 C14513 C14552 C14553 C14554 C14576 C14577 C14581 C14582 C14600 C14603 C14670 C14671 C14673 C14703 C16709 C16710 C16713 C16716 C16717 C16727 C16728 C16737 C16743 C16747 C16748 C16761 C16763 C16764 C16773 C16777 C16779 C16785 C16788	P9064 P9386 P12261 P14488 P14513 P14552 P14553 P14554 P14576 P14577 P14581 P14582 P14600 P14603 P14670 P14671 P14673 P14703 P16709 P16710 P16713 P16716 P16717 P16727 P16728 P16737 P16743 P16747 P16748 P16761 P16763 P16764 P16773 P16777 P16779 P16785 P16788	1	3	1	
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection	Nepexto	GQ	MP	C8879 C9081 C12123 C14499 C14507 C14629 C14683 C14701 C14715 C16718 C16720 C16725 C16750 C16753 C16754 C16765	P8879 P9081 P12123 P14499 P14507 P14629 P14683 P14701 P14715 P16718 P16720 P16725 P16750 P16753 P16754 P16765	1	5	1	

						C16766 C16772 C16774 C16775 C16778 C16787 C16789 C16792 C16795	P16766 P16772 P16774 P16775 P16778 P16787 P16789 P16792 P16795				
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Brenzys	RF	MP	C9064 C14488 C14581 C14582 C14603 C14670 C14671 C14673 C14703 C16709 C16710 C16713 C16716 C16717 C16737 C16743 C16747 C16748 C16761 C16763 C16764 C16773 C16779 C16785 C16788	P9064 P14488 P14581 P14582 P14603 P14670 P14671 P14673 P14703 P16709 P16710 P16713 P16716 P16717 P16737 P16743 P16747 P16748 P16761 P16763 P16764 P16773 P16779 P16785 P16788	1	3	1	
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Brenzys	RF	MP	C8879 C9081 C14499 C14507 C14629 C14683 C14701 C14715 C16720 C16725 C16750 C16753 C16754 C16765 C16766 C16772 C16774 C16778 C16789 C16792 C16795	P8879 P9081 P14499 P14507 P14629 P14683 P14701 P14715 P16720 P16725 P16750 P16753 P16754 P16765 P16766 P16772 P16774 P16778 P16789 P16792 P16795	1	5	1	
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	PF	MP	C9417 C14068 C14070 C14071 C14154 C14155	See Note 3	See Note 3	See Note 3	1	C(100)
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	PF	MP	C14508 C14509	P14508 P14509	1	1	1	
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	PF	MP	C9064 C9386 C12261 C14488 C14513 C14552 C14553 C14554 C14576 C14577	P9064 P9386 P12261 P14488 P14513 P14552 P14553 P14554 P14576 P14577	1	3	1	

						C14600 C14703 C16709 C16710 C16713 C16716 C16717 C16727 C16728 C16737 C16743 C16747 C16748 C16761 C16763 C16764 C16773 C16777 C16779 C16785 C16788	P14600 P14703 P16709 P16710 P16713 P16716 P16717 P16727 P16728 P16737 P16743 P16747 P16748 P16761 P16763 P16764 P16773 P16777 P16779 P16785 P16788			
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Enbrel	PF	MP	C8879 C9081 C12123 C14499 C14507 C14715 C16718 C16725 C16750 C16753 C16754 C16765 C16766 C16772 C16774 C16775 C16789 C16792	P8879 P9081 P12123 P14499 P14507 P14715 P16718 P16725 P16750 P16753 P16754 P16765 P16766 P16772 P16774 P16775 P16789 P16792	1	5	1

[24] Schedule 1, Part 1, entries for Ezetimibe

omit:

Ezetimibe	Tablet 10 mg (S19A)	Oral	Ezetimibe USP (Camber, USA)	RQ	MP NP			30	5	90
Ezetimibe	Tablet 10 mg (S19A)	Oral	Ezetimibe USP (Camber, USA)	RQ	MP NP		P14238	60	5	90

[25] Schedule 1, Part 1, entries for Ezetimibe with simvastatin in the form Tablet 10 mg-10 mg

omit:

Ezetimibe with simvastatin	Tablet 10 mg-10 mg	Oral	Zeklen 10/10 mg	AF	MP NP			30	5	30
Ezetimibe with simvastatin	Tablet 10 mg-10 mg	Oral	Zeklen 10/10 mg	AF	MP NP		P14238	60	5	30

[26] Schedule 1, Part 1, entries for Ezetimibe with simvastatin in the form Tablet 10 mg-20 mg

omit:

Ezetimibe with simvastatin	Tablet 10 mg-20 mg	Oral	Zeklen 10/20 mg	AF	MP NP		30	5	30
Ezetimibe with simvastatin	Tablet 10 mg-20 mg	Oral	Zeklen 10/20 mg	AF	MP NP	P14238	60	5	30

[27] Schedule 1, Part 1, entries for Ezetimibe with simvastatin in the form Tablet 10 mg-40 mg

omit:

Ezetimibe with simvastatin	Tablet 10 mg-40 mg	Oral	Zeklen 10/40 mg	AF	MP NP		30	5	30
Ezetimibe with simvastatin	Tablet 10 mg-40 mg	Oral	Zeklen 10/40 mg	AF	MP NP	P14238	60	5	30

[28] Schedule 1, Part 1, entries for Ezetimibe with simvastatin in the form Tablet 10 mg-80 mg

omit:

Ezetimibe with simvastatin	Tablet 10 mg-80 mg	Oral	Zeklen 10/80 mg	AF	MP NP		30	5	30
Ezetimibe with simvastatin	Tablet 10 mg-80 mg	Oral	Zeklen 10/80 mg	AF	MP NP	P14238	60	5	30

[29] Schedule 1, Part 1, entry for Faricimab in the form Solution for intravitreal injection 21 mg in 0.175 mL (120 mg per mL) pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 2]*

(a) insert in numerical order in the column headed "Circumstances": C13336 C13387

(b) insert in numerical order in the column headed "Circumstances": C16309 C16319

(c) insert in numerical order in the column headed "Purposes": P13336 P13387

(d) insert in numerical order in the column headed "Purposes": P16309 P16319

[30] Schedule 1, Part 1, entries for Felodipine in the form Tablet 2.5 mg (extended release)

omit:

Felodipine	Tablet 2.5 mg (extended release)	Oral	Fendex ER	AF	MP NP			30	5	30
Felodipine	Tablet 2.5 mg (extended release)	Oral	Fendex ER	AF	MP NP		P14238	60	5	30

[31] Schedule 1, Part 1, entries for Felodipine in the form Tablet 5 mg (extended release)

omit:

Felodipine	Tablet 5 mg (extended release)	Oral	Fendex ER	AF	MP NP			30	5	30
Felodipine	Tablet 5 mg (extended release)	Oral	Fendex ER	AF	MP NP		P14238	60	5	30

[32] Schedule 1, Part 1, entries for Felodipine in the form Tablet 10 mg (extended release)

omit:

Felodipine	Tablet 10 mg (extended release)	Oral	Fendex ER	AF	MP NP			30	5	30
Felodipine	Tablet 10 mg (extended release)	Oral	Fendex ER	AF	MP NP		P14238	60	5	30

[33] Schedule 1, Part 1, after entry for Fingolimod in the form Capsule 500 micrograms (as hydrochloride) *[Brand: AKM Fingolimod]*

insert:

Fingolimod	Capsule 500 micrograms (as hydrochloride)	Oral	FILOSIR	NM	MP NP	C16301 C16323		28	5	28

[34] Schedule 1, Part 1, entries for Gliclazide in the form Tablet 30 mg (modified release)

omit:

Gliclazide	Tablet 30 mg (modified release)	Oral	Glyade MR	AF	MP NP			100	5	100
Gliclazide	Tablet 30 mg (modified release)	Oral	Glyade MR	AF	MP NP		P14238	200	5	100

[35] Schedule 1, Part 1, entries for Glimepiride in the form Tablet 1 mg

omit:

Glimepiride	Tablet 1 mg	Oral	Glimepiride APOTEX	GX	MP NP		30	5	30
Glimepiride	Tablet 1 mg	Oral	Glimepiride APOTEX	GX	MP NP	P14238	60	5	30

[36] Schedule 1, Part 1, entries for Glimepiride in the form Tablet 2 mg

omit:

Glimepiride	Tablet 2 mg	Oral	Glimepiride APOTEX	GX	MP NP		30	5	30
Glimepiride	Tablet 2 mg	Oral	Glimepiride APOTEX	GX	MP NP	P14238	60	5	30

[37] Schedule 1, Part 1, entries for Glimepiride in the form Tablet 3 mg

omit:

Glimepiride	Tablet 3 mg	Oral	Glimepiride APOTEX	GX	MP NP		30	5	30
Glimepiride	Tablet 3 mg	Oral	Glimepiride APOTEX	GX	MP NP	P14238	60	5	30

[38] Schedule 1, Part 1, entries for Glimepiride in the form Tablet 4 mg

omit:

Glimepiride	Tablet 4 mg	Oral	Glimepiride APOTEX	GX	MP NP		30	5	30
Glimepiride	Tablet 4 mg	Oral	Glimepiride APOTEX	GX	MP NP	P14238	60	5	30

[39] Schedule 1, Part 1, entries for Glyceryl trinitrate

omit:

Glyceryl trinitrate	Transdermal patch 54 mg	Transdermal	Minitran 15	IL	MP NP			30	5	30	
Glyceryl trinitrate	Transdermal patch 54 mg	Transdermal	Minitran 15	IL	MP NP		P14238	60	5	30	

[40] Schedule 1, Part 1, entries for Imiquimod in the form Cream 50 mg per g, 250 mg single use sachets, 12

omit:

Imiquimod	Cream 50 mg per g, 250 mg single use sachets, 12	Application	Aldiq	AF	MP	C4229		1	1	1	

[41] Schedule 1, Part 1, entries for Ipratropium in the form Nebuliser solution containing ipratropium bromide 250 micrograms (as monohydrate) in 1 mL single dose units, 30

omit:

Ipratropium	Nebuliser solution containing ipratropium bromide 250 micrograms (as monohydrate) in 1 mL single dose units, 30	Inhalation	Ipratrin	AF	MP NP	C6331 C6341		2	5	1	

[42] Schedule 1, Part 1, entries for Ipratropium in the form Nebuliser solution containing ipratropium bromide 500 micrograms (as monohydrate) in 1 mL single dose units, 30

omit:

Ipratropium	Nebuliser solution containing ipratropium bromide 500 micrograms (as monohydrate) in 1 mL single dose units, 30	Inhalation	Ipratrin Adult	AF	MP NP	C6331 C6341		2	5	1	

[43] Schedule 1, Part 1, entries for Irinotecan

omit:

Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL	Injection	Omegapharm Irinotecan	OE	MP			See Note 3	See Note 3	1	D(100)

[44] Schedule 1, Part 1, entries for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL

(a) omit:

Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL	Injection	Irinotecan Alphapharm	AF	MP		See Note 3	See Note 3	1	D(100)

(b) insert after entry for "IRINOTECAN BAXTER":

Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL	Injection	IRINOTECAN EUGIA	YG	MP		See Note 3	See Note 3	1	D(100)

(c) omit:

Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL	Injection	Omegapharm Irinotecan	OE	MP		See Note 3	See Note 3	1	D(100)

[45] Schedule 1, Part 1, entries for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL

(a) omit:

Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL	Injection	Irinotecan Alphapharm	AF	MP		See Note 3	See Note 3	1	D(100)

(b) insert after entry for "Irinotecan Accord":

Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL	Injection	IRINOTECAN EUGIA	YG	MP		See Note 3	See Note 3	1	D(100)

[46] Schedule 1, Part 1, after entry for Ivermectin in the form Tablet 3 mg *[Maximum Quantity: 8; Number of Repeats: 2]*

insert:

Ivosidenib	Tablet 250 mg	Oral	Tibsovo	SE	MP	C16701	60	5	60	

[47] Schedule 1, Part 1, entries for Leflunomide in the form Tablet 10 mg

omit:

Leflunomide	Tablet 10 mg	Oral	Leflunomide APOTEX	GX	MP	C13753 C13771	P13753 P13771	30	5	30
Leflunomide	Tablet 10 mg	Oral	Leflunomide APOTEX	GX	MP	C14941 C14942	P14941 P14942	60	5	30

[48] Schedule 1, Part 1, entries for Leflunomide in the form Tablet 20 mg

omit:

Leflunomide	Tablet 20 mg	Oral	Leflunomide APOTEX	GX	MP	C13753 C13771	P13753 P13771	30	5	30
Leflunomide	Tablet 20 mg	Oral	Leflunomide APOTEX	GX	MP	C14941 C14942	P14941 P14942	60	5	30

[49] Schedule 1, Part 1, entries for Lercanidipine in the form Tablet containing lercanidipine hydrochloride 10 mg

omit:

Lercanidipine	Tablet containing lercanidipine hydrochloride 10 mg	Oral	Lercanidipine APOTEX	GX	MP NP			28	5	28
Lercanidipine	Tablet containing lercanidipine hydrochloride 10 mg	Oral	Lercanidipine APOTEX	GX	MP NP		P14238	56	5	28

[50] Schedule 1, Part 1, entries for Letrozole

omit:

Letrozole	Tablet 2.5 mg	Oral	Letrozole APOTEX	GX	MP NP	C5522	P5522	30	5	30
Letrozole	Tablet 2.5 mg	Oral	Letrozole APOTEX	GX	MP NP	C14895	P14895	60	5	30

[51] Schedule 1, Part 1, entries for Levetiracetam in the form Tablet 250 mg

(a) omit:

Levetiracetam	Tablet 250 mg	Oral	Kevtam 250	AF	MP NP	C16582	P16582	60	5	60
Levetiracetam	Tablet 250 mg	Oral	Kevtam 250	AF	MP NP	C16615	P16615	120	5	60

(b) omit:

Levetiracetam	Tablet 250 mg	Oral	Levetiracetam Mylan	AL	MP NP	C16582	P16582	60	5	60
Levetiracetam	Tablet 250 mg	Oral	Levetiracetam Mylan	AL	MP NP	C16615	P16615	120	5	60

[52] Schedule 1, Part 1, entries for Levetiracetam in the form Tablet 500 mg

omit:

Levetiracetam	Tablet 500 mg	Oral	Kevtam 500	AF	MP NP	C16582	P16582	60	5	60
Levetiracetam	Tablet 500 mg	Oral	Kevtam 500	AF	MP NP	C16615	P16615	120	5	60

[53] Schedule 1, Part 1, entries for Levetiracetam in the form Tablet 1 g

(a) omit:

Levetiracetam	Tablet 1 g	Oral	Kevtam 1000	AF	MP NP	C16582	P16582	60	5	60
Levetiracetam	Tablet 1 g	Oral	Kevtam 1000	AF	MP NP	C16615	P16615	120	5	60

(b) omit:

Levetiracetam	Tablet 1 g	Oral	Levetiracetam Mylan	AL	MP NP	C16582	P16582	60	5	60
Levetiracetam	Tablet 1 g	Oral	Levetiracetam Mylan	AL	MP NP	C16615	P16615	120	5	60

[54] Schedule 1, Part 1, entries for Lurasidone in the form Tablet containing lurasidone hydrochloride 40 mg

omit:

Lurasidone	Tablet containing lurasidone hydrochloride 40 mg	Oral	Latuda	SE	MP NP	C4246	30	5	30	

[55] Schedule 1, Part 1, entries for Lurasidone in the form Tablet containing lurasidone hydrochloride 80 mg

omit:

Lurasidone	Tablet containing lurasidone hydrochloride 80 mg	Oral	Latuda	SE	MP NP	C4246	30	5	30	

[56] Schedule 1, Part 1, after entry for Maraviroc in the form Tablet 300 mg *[Brand: Maraviroc Waymade]*

insert:

Maribavir	Tablet 200 mg	Oral	Livtencity	TK	MP	C16735 C16806	112	1	28	D(100)

[57] Schedule 1, Part 1, after entry for Methadone in the form Tablet containing methadone hydrochloride 10 mg *[Brand: Physeptone; Maximum Quantity: 120; Number of Repeats: 0]*

insert:

Methenamine	Tablet containing methenamine hippurate 1 g	Oral	APOHEALTH Urinary Tract Antibacterial	TX	MP NP		100	5	100	
Methenamine	Tablet containing methenamine hippurate 1 g	Oral	APOHEALTH Urinary Tract Antibacterial	TX	MP NP	P14238	200	5	100	
Methenamine	Tablet containing methenamine hippurate 1 g	Oral	Chemists' Own Urinary Tract Antibacterial	RW	MP NP		100	5	100	
Methenamine	Tablet containing methenamine hippurate 1 g	Oral	Chemists' Own Urinary Tract Antibacterial	RW	MP NP	P14238	200	5	100	

[58] Schedule 1, Part 1, after entry for Methylphenidate in the form Tablet containing methylphenidate hydrochloride 18 mg (extended release) *[Brand: METHYLPHENIDATE-TEVA XR]*

insert:

Methylphenidate	Tablet containing methylphenidate hydrochloride 18 mg (extended release) Concerta (Switzerland) (S19A)	Oral	Concerta (Switzerland)	DZ	MP NP	C16598	30	5	60
Methylphenidate	Tablet containing methylphenidate hydrochloride 18 mg (extended release) (S19A)	Oral	Concerta (Switzerland)	DZ	MP NP	C16598	30	5	30

[59] Schedule 1, Part 1, after entry for Methylphenidate in the form Tablet containing methylphenidate hydrochloride 27 mg (extended release) *[Brand: METHYLPHENIDATE-TEVA XR]*

insert:

Methylphenidate	Tablet containing methylphenidate hydrochloride 27 mg (extended release) (S19A)	Oral	Concerta (Switzerland)	DZ	MP NP	C16598	30	5	30

[60] Schedule 1, Part 1, after entry for Methylphenidate in the form Tablet containing methylphenidate hydrochloride 36 mg (extended release) *[Brand: METHYLPHENIDATE-TEVA XR]*

insert:

Methylphenidate	Tablet containing methylphenidate hydrochloride 36 mg (extended release) Concerta (Switzerland) (S19A)	Oral	Concerta (Switzerland)	DZ	MP NP	C16598	30	5	60
Methylphenidate	Tablet containing methylphenidate hydrochloride 36 mg (extended release) (S19A)	Oral	Concerta (Switzerland)	DZ	MP NP	C16598	30	5	30

[61] Schedule 1, Part 1, after entry for Methylphenidate in the form Tablet containing methylphenidate hydrochloride 54 mg (extended release) *[Brand: METHYLPHENIDATE-TEVA XR]*

insert:

Methylphenidate	Tablet containing methylphenidate hydrochloride 54 mg (extended release) Concerta (Switzerland) (S19A)	Oral	Concerta (Switzerland)	DZ	MP NP	C16598		30	5	60
Methylphenidate	Tablet containing methylphenidate hydrochloride 54 mg (extended release) (S19A)	Oral	Concerta (Switzerland)	DZ	MP NP	C16598		30	5	30

[62] Schedule 1, Part 1, entries for Morphine in the form Tablet containing morphine sulfate pentahydrate 10 mg (controlled release)

omit:

Morphine	Tablet containing morphine sulfate pentahydrate 10 mg (controlled release)	Oral	Morphine MR Mylan	AF	MP NP	C10748 C10752 C10755	P10748 P10752 P10755	28	0	V10748 V10752 V10755	28
Morphine	Tablet containing morphine sulfate pentahydrate 10 mg (controlled release)	Oral	Morphine MR Mylan	AF	MP NP	C11753	P11753	56	0	V11753	28

[63] Schedule 1, Part 1, entries for Morphine in the form Tablet containing morphine sulfate pentahydrate 30 mg (controlled release)

omit:

Morphine	Tablet containing morphine sulfate pentahydrate 30 mg (controlled release)	Oral	Morphine MR Mylan	AF	MP NP	C10748 C10752 C10755	P10748 P10752 P10755	28	0	V10748 V10752 V10755	28
Morphine	Tablet containing morphine sulfate pentahydrate 30 mg (controlled release)	Oral	Morphine MR Mylan	AF	MP NP	C11753	P11753	56	0	V11753	28

[64] Schedule 1, Part 1, entries for Morphine in the form Tablet containing morphine sulfate pentahydrate 60 mg (controlled release)

omit:

Morphine	Tablet containing morphine sulfate pentahydrate 60 mg (controlled release)	Oral	Morphine MR Mylan	AF	MP NP	C10748 C10752 C10755	P10748 P10752 P10755	28	0	V10748 V10752 V10755	28
Morphine	Tablet containing morphine sulfate pentahydrate 60 mg (controlled release)	Oral	Morphine MR Mylan	AF	MP NP	C11753	P11753	56	0	V11753	28

[65] Schedule 1, Part 1, entries for Morphine in the form Tablet containing morphine sulfate pentahydrate 100 mg (controlled release)

omit:

Morphine	Tablet containing morphine sulfate pentahydrate 100 mg (controlled release)	Oral	Morphine MR Mylan	AF	MP NP	C10748 C10752 C10755	P10748 P10752 P10755	28	0	V10748 V10752 V10755	28
Morphine	Tablet containing morphine sulfate pentahydrate 100 mg (controlled release)	Oral	Morphine MR Mylan	AF	MP NP	C11753	P11753	56	0	V11753	28

[66] Schedule 1, Part 1, after entry for Naproxen in the form Oral suspension 125 mg per 5 mL, 474 mL

insert:

Naproxen	Oral suspension 125 mg per 5 mL, 474 mL (S19A)	Oral	Pediapharm Naproxen Suspension 25 mg/mL (Medexus Pharma, Canada)	KQ	MP NP	C4124 C4159 C6150		1	3		1

[67] Schedule 1, Part 1, entries for Nivolumab in each of the forms: Injection concentrate for I.V. infusion 40 mg in 4 mL; and Injection concentrate for I.V. infusion 100 mg in 10 mL

(a) insert in numerical order in the column headed "Circumstances": C16755 C16790

(b) insert in numerical order in the column headed "Variations": V16755

[68] Schedule 1, Part 1, entries for Norfloxacin

omit:

Norfloxacin	Tablet 400 mg	Oral	Nufloxib	AF	MP NP	C5744 C5806		14	1		14

[69] Schedule 1, Part 1, entries for Olanzapine in the form Tablet 2.5 mg

omit:

Olanzapine	Tablet 2.5 mg	Oral	Olanzapine APOTEX	GX	MP NP	C4246 C5869	28	5	28

[70] Schedule 1, Part 1, entry for Olaparib in the form Tablet 100 mg *[Maximum Quantity: 112; Number of Repeats: 5]*

(a) omit from the column headed "Circumstances": C16240

(b) insert in numerical order in the column headed "Circumstances": C16780

(c) omit from the column headed "Purposes": P16240

(d) insert in numerical order in the column headed "Purposes": P16780

[71] Schedule 1, Part 1, entry for Olaparib in the form Tablet 100 mg *[Maximum Quantity: 112; Number of Repeats: 6]*

(a) omit from the column headed "Circumstances": C15371 *substitute:* C16757

(b) omit from the column headed "Purposes": P15371 *substitute:* P16757

[72] Schedule 1, Part 1, entry for Olaparib in the form Tablet 150 mg *[Maximum Quantity: 112; Number of Repeats: 5]*

(a) omit from the column headed "Circumstances": C16240

(b) insert in numerical order in the column headed "Circumstances": C16780

(c) omit from the column headed "Purposes": P16240

(d) insert in numerical order in the column headed "Purposes": P16780

[73] Schedule 1, Part 1, entry for Olaparib in the form Tablet 150 mg *[Maximum Quantity: 112; Number of Repeats: 6]*

(a) omit from the column headed "Circumstances": C15371 *substitute:* C16757

(b) omit from the column headed "Purposes": P15371 *substitute:* P16757

[74] Schedule 1, Part 1, entries for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate)

omit:

Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	Oral	Pantoprazole APOTEX	TY	MP NP	C8774 C8775	P8774 P8775	30	1	30
Pantoprazole	Tablet (enteric coated)	Oral	Pantoprazole	TY	MP	C8776 C8780	P8776 P8780	30	5	30

	40 mg (as sodium sesquihydrate)		APOTEX		NP	C8866	P8866			
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	Oral	Pantoprazole APOTEX	TY	MP	C11310	P11310	60	5	30
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	Oral	Pantoprazole APOTEX	TY	MP NP	C15530 C15658 C15678	P15530 P15658 P15678	60	5	30
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	Oral	Pantoprazole APOTEX	TY	MP	C15856	P15856	120	5	30

[75] Schedule 1, Part 1, entry for Ribociclib *[Maximum Quantity: 21; Number of Repeats: 5]*

(a) insert in numerical order in the column headed "Circumstances": C16809

(b) insert in numerical order in the column headed "Purposes": P16809

[76] Schedule 1, Part 1, entry for Ribociclib *[Maximum Quantity: 42; Number of Repeats: 5]*

(a) insert in numerical order in the column headed "Circumstances": C16808

(b) insert in numerical order in the column headed "Purposes": P16808

[77] Schedule 1, Part 1, after entry for Rituximab in the form Solution for I.V. infusion 500 mg in 50 mL *[Brand: Truxima; Maximum Quantity: See Note 3; Number of Repeats: See Note 3]*

insert:

Rivaroxaban	Tablet 2.5 mg	Oral	APO-Rivaroxaban	TX	MP NP	C10992	P10992	60	5	60
Rivaroxaban	Tablet 2.5 mg	Oral	APO-Rivaroxaban	TX	MP	C11013	P11013	60	5	60
Rivaroxaban	Tablet 2.5 mg	Oral	APO-Rivaroxaban	TX	MP NP	C14298	P14298	120	5	60

[78] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 2.5 mg *[Brand: Xarelto; Maximum Quantity: 120; Number of Repeats: 5]*

insert:

Rivaroxaban	Tablet 10 mg	Oral	APO-Rivaroxaban	TX	MP NP	C4382	P4382	15	0	15
Rivaroxaban	Tablet 10 mg	Oral	APO-Rivaroxaban	TX	MP NP	C4402	P4402	15	1	15
Rivaroxaban	Tablet 10 mg	Oral	APO-Rivaroxaban	TX	MP NP	C4402	P4402	30	0	30
Rivaroxaban	Tablet 10 mg	Oral	APO-Rivaroxaban	TX	MP NP	C4132	P4132	30	5	30
Rivaroxaban	Tablet 10 mg	Oral	APO-Rivaroxaban	TX	MP NP	C14300	P14300	60	5	30

[79] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 10 mg *[Brand: iXarola; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Rivaroxaban	Tablet 10 mg	Oral	Rivarelto	XW	MP NP	C4402	P4402	30	0	30
Rivaroxaban	Tablet 10 mg	Oral	Rivarelto	XW	MP NP	C4132	P4132	30	5	30
Rivaroxaban	Tablet 10 mg	Oral	Rivarelto	XW	MP NP	C14300	P14300	60	5	30

[80] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 10 mg *[Brand: Xarelto; Maximum Quantity: 60; Number of Repeats: 5]*

insert:

Rivaroxaban	Tablet 15 mg	Oral	APO-Rivaroxaban	TX	MP NP	C4269	P4269	28	5	28
Rivaroxaban	Tablet 15 mg	Oral	APO-Rivaroxaban	TX	MP NP	C4098 C5098	P4098 P5098	42	0	42
Rivaroxaban	Tablet 15 mg	Oral	APO-Rivaroxaban	TX	MP NP	C14301	P14301	56	5	28

[81] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 15 mg *[Brand: iXarola; Maximum Quantity: 56; Number of Repeats: 5]*

insert:

Rivaroxaban	Tablet 15 mg	Oral	Rivarelto	XW	MP NP	C4269	P4269	28	5	28
Rivaroxaban	Tablet 15 mg	Oral	Rivarelto	XW	MP NP	C4098 C5098	P4098 P5098	42	0	42
Rivaroxaban	Tablet 15 mg	Oral	Rivarelto	XW	MP NP	C14301	P14301	56	5	28

[82] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 15 mg *[Brand: Xarelto; Maximum Quantity: 56; Number of Repeats: 5]*

insert:

Rivaroxaban	Tablet 20 mg	Oral	APO-Rivaroxaban	TX	MP NP	C4099 C4132 C4268 C4269	P4099 P4132 P4268 P4269	28	5	28
Rivaroxaban	Tablet 20 mg	Oral	APO-Rivaroxaban	TX	MP NP	C14264 C14300 C14301 C14318	P14264 P14300 P14301 P14318	56	5	28

[83] Schedule 1, Part 1, after entry for Rivaroxaban in the form Tablet 20 mg *[Brand: iXarola; Maximum Quantity: 56; Number of Repeats: 5]*

insert:

Rivaroxaban	Tablet 20 mg	Oral	Rivarelto	XW	MP NP	C4099 C4132 C4268 C4269	P4099 P4132 P4268 P4269	28	5	28
Rivaroxaban	Tablet 20 mg	Oral	Rivarelto	XW	MP NP	C14264 C14300 C14301 C14318	P14264 P14300 P14301 P14318	56	5	28

[84] Schedule 1, Part 1, entries for Rosuvastatin in the form Tablet 20 mg (as calcium)

omit:

Rosuvastatin	Tablet 20 mg (as calcium)	Oral	Rosuvastatin APOTEX	GX	MP NP			30	5	30
Rosuvastatin	Tablet 20 mg (as calcium)	Oral	Rosuvastatin APOTEX	GX	MP NP		P14238	60	5	30

[85] Schedule 1, Part 1, entries for Rosuvastatin in the form Tablet 40 mg (as calcium)

omit:

Rosuvastatin	Tablet 40 mg (as calcium)	Oral	Rosuvastatin APOTEX	GX	MP NP			30	5	30
Rosuvastatin	Tablet 40 mg (as calcium)	Oral	Rosuvastatin APOTEX	GX	MP NP		P14238	60	5	30

[86] Schedule 1, Part 1, after entry for Sacubitril with valsartan in the form Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg *[Brand: Entresto; Maximum Quantity: 112; Number of Repeats: 5]*

insert:

Sacubitril with valsartan	Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg	Oral	Omtralo	NM	MP NP	C11680	P11680	56	5	56
Sacubitril with valsartan	Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg	Oral	Omtralo	NM	MP NP	C14254	P14254	112	5	56

[87] Schedule 1, Part 1, after entry for Sacubitril with valsartan in the form Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg *[Brand: Pharmacor Sacubitril/Valsartan; Maximum Quantity: 112; Number of Repeats: 5]*

insert:

Sacubitril with valsartan	Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg	Oral	Sacubitril/Valsartan Alphapharm	FY	MP NP	C11680	P11680	56	5	56
Sacubitril with valsartan	Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg	Oral	Sacubitril/Valsartan Alphapharm	FY	MP NP	C14254	P14254	112	5	56

[88] Schedule 1, Part 1, entries for Sacubitril with valsartan in the form Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg *[Brand: Valtresto]*

omit from the column headed "Responsible Person" (all instances): RM *substitute (all instances):* TX

[89] Schedule 1, Part 1, after entry for Sacubitril with valsartan in the form Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg *[Brand: Entresto; Maximum Quantity: 112; Number of Repeats: 5]*

insert:

Sacubitril with valsartan	Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg	Oral	Omtralo	NM	MP NP	C11680	P11680	56	5	56
Sacubitril with valsartan	Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg	Oral	Omtralo	NM	MP NP	C14254	P14254	112	5	56

[90] Schedule 1, Part 1, after entry for Sacubitril with valsartan in the form Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg *[Brand: Pharmacor Sacubitril/Valsartan; Maximum Quantity: 112; Number of Repeats: 5]*

insert:

Sacubitril with valsartan	Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg	Oral	Sacubitril/Valsartan Alphapharm	FY	MP NP	C11680	P11680	56	5	56
Sacubitril with valsartan	Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg	Oral	Sacubitril/Valsartan Alphapharm	FY	MP NP	C14254	P14254	112	5	56

[91] Schedule 1, Part 1, entries for Sacubitril with valsartan in the form Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg *[Brand: Valtresto]*

omit from the column headed "Responsible Person" (all instances): RM *substitute (all instances):* TX

[92] Schedule 1, Part 1, after entry for Sacubitril with valsartan in the form Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg *[Brand: Entresto; Maximum Quantity: 112; Number of Repeats: 5]*

insert:

Sacubitril with valsartan	Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg	Oral	Omtralo	NM	MP NP	C11680	P11680	56	5	56
Sacubitril with valsartan	Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg	Oral	Omtralo	NM	MP NP	C14254	P14254	112	5	56

[93] Schedule 1, Part 1, after entry for Sacubitril with valsartan in the form Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg *[Brand: Pharmacor Sacubitril/Valsartan; Maximum Quantity: 112; Number of Repeats: 5]*

insert:

Sacubitril with valsartan	Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg	Oral	Sacubitril/Valsartan Alphapharm	FY	MP NP	C11680	P11680	56	5	56	
Sacubitril with valsartan	Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg	Oral	Sacubitril/Valsartan Alphapharm	FY	MP NP	C14254	P14254	112	5	56	

[94] Schedule 1, Part 1, entries for Sacubitril with valsartan in the form Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg *[Brand: Valtresto]*

omit from the column headed "Responsible Person" (all instances): RM *substitute (all instances):* TX

[95] Schedule 1, Part 1, entries for Sevelamer in the form Tablet containing sevelamer carbonate 800 mg

omit:

Sevelamer	Tablet containing sevelamer carbonate 800 mg	Oral	Sevelamer Apotex	TX	MP NP	C5491	P5491	180	5	180	
Sevelamer	Tablet containing sevelamer carbonate 800 mg	Oral	Sevelamer Apotex	TX	MP	C5530 C9762	P5530 P9762	360	5	180	C(100)
Sevelamer	Tablet containing sevelamer carbonate 800 mg	Oral	Sevelamer Apotex	TX	MP NP	C14872	P14872	360	5	180	

[96] Schedule 1, Part 1, entries for Sumatriptan in the form Tablet 50 mg (as succinate)

(a) omit:

Sumatriptan	Tablet 50 mg (as succinate)	Oral	Imigran	LN	MP NP	C5141	4	5	2	

(b) omit:

Sumatriptan	Tablet 50 mg (as succinate)	Oral	IMIGRAN MIGRAINE	AS	MP NP	C5141	4	5	2	

[97] Schedule 1, Part 1, entry for Trastuzumab in the form Powder for I.V. infusion 420 mg

omit from the column headed "Responsible Person": JU *substitute:* XT

[98] Schedule 1, Part 2, after entry for Glyceryl trinitrate

insert:

Glyceryl trinitrate	Transdermal patch 54 mg	Transdermal	Minitran 15	IL	30

[99] Schedule 1, Part 2, omit entries for Hypromellose with carbomer 980

[100] Schedule 3, after entry for Responsible Person code FX

insert:

FY	Pharmacor Pty Limited	58 121 020 835

[101] Schedule 3, after entry for Responsible Person code KY

insert:

LD	Lacuna Pharma Pty Ltd	12 646 520 792

[102] Schedule 3

omit:

OE	Omegapharm Pty Ltd	86 128 078 151

[103] Schedule 3

omit:

RM	Pharmacor Pty Limited	58 121 020 835

[104] Schedule 4, Part 1, omit entry for Circumstances Code "C7289"

[105] Schedule 4, Part 1, omit entry for Circumstances Code "C8839"

[106] Schedule 4, Part 1, omit entry for Circumstances Code "C8842"

[107] Schedule 4, Part 1, omit entry for Circumstances Code "C8873"

[108] Schedule 4, Part 1, omit entry for Circumstances Code "C8887"

[109] Schedule 4, Part 1, omit entry for Circumstances Code "C8955"

[110] **Schedule 4, Part 1, omit entry for Circumstances Code "C9123"**

[111] **Schedule 4, Part 1, omit entry for Circumstances Code "C9140"**

[112] **Schedule 4, Part 1, omit entry for Circumstances Code "C9156"**

[113] **Schedule 4, Part 1, omit entry for Circumstances Code "C9162"**

[114] **Schedule 4, Part 1, omit entry for Circumstances Code "C9377"**

[115] **Schedule 4, Part 1, entry for Circumstances Code "C9380"**

omit from the column headed "Listed Drug": Etanercept

[116] **Schedule 4, Part 1, omit entry for Circumstances Code "C9388"**

[117] **Schedule 4, Part 1, omit entry for Circumstances Code "C9473"**

[118] **Schedule 4, Part 1, entry for Circumstances Code "C11107"**

omit from the column headed "Listed Drug": Etanercept

[119] **Schedule 4, Part 1, entry for Circumstances Code "C12123"**

insert in alphabetical order in the column headed "Listed Drug": Etanercept

[120] **Schedule 4, Part 1, omit entry for Circumstances Code "C12164"**

[121] **Schedule 4, Part 1, omit entry for Circumstances Code "C13532"**

[122] **Schedule 4, Part 1, omit entry for Circumstances Code "C13533"**

[123] **Schedule 4, Part 1, omit entry for Circumstances Code "C13538"**

[124] **Schedule 4, Part 1, omit entry for Circumstances Code "C13593"**

[125] **Schedule 4, Part 1, omit entry for Circumstances Code "C13598"**

[126] **Schedule 4, Part 1, omit entry for Circumstances Code "C13646"**

[127] **Schedule 4, Part 1, omit entry for Circumstances Code "C13647"**

[128] **Schedule 4, Part 1, omit entry for Circumstances Code "C14382"**

[129] **Schedule 4, Part 1, omit entry for Circumstances Code "C14427"**

[130] Schedule 4, Part 1, entry for Circumstances Code "C14483"

omit from the column headed "Listed Drug": Etanercept

[131] Schedule 4, Part 1, entry for Circumstances Code "C14486"

omit from the column headed "Listed Drug": Etanercept

[132] Schedule 4, Part 1, entry for Circumstances Code "C14493"

omit from the column headed "Listed Drug": Etanercept

[133] Schedule 4, Part 1, entry for Circumstances Code "C14498"

omit from the column headed "Listed Drug": Etanercept

[134] Schedule 4, Part 1, entry for Circumstances Code "C14655"

omit from the column headed "Listed Drug": Etanercept

[135] Schedule 4, Part 1, entry for Circumstances Code "C14656"

omit from the column headed "Listed Drug": Etanercept

[136] Schedule 4, Part 1, entry for Circumstances Code "C14662"

omit from the column headed "Listed Drug": Etanercept

[137] Schedule 4, Part 1, entry for Circumstances Code "C14713"

omit from the column headed "Listed Drug": Etanercept

[138] Schedule 4, Part 1, omit entry for Circumstances Code "C15186"

[139] Schedule 4, Part 1, omit entry for Circumstances Code "C15371"

[140] Schedule 4, Part 1, entry for Circumstances Code "C15527"

substitute:

C15527	P15527	CN15527	Nivolumab	Urothelial carcinoma The treatment must be for each of: (i) adjuvant therapy that is/was initiated within 120 days of radical surgical resection, (ii) muscle invasive type disease, (iii) disease considered to be at high risk of recurrence based on pathologic staging of radical surgery tissue (ypT2-ypT4a or ypN+), but yet to recur, (iv) use as the sole PBS-subsidised anti-cancer treatment for this condition; AND	Compliance with Authority Required procedures

				Patient must have received prior platinum containing neoadjuvant chemotherapy; AND Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1. Patient must be undergoing treatment with a dosing regimen as set out in the drug's Therapeutic Goods Administration (TGA) approved Product Information; AND Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.	

[141] Schedule 4, Part 1, omit entry for Circumstances Code "C16240"

[142] Schedule 4, Part 1, after entry for Circumstances Code "C16699"

insert:

C16701	P16701	CN16701	Ivosidenib	Locally advanced or metastatic cholangiocarcinoma Patient must have a test of tumour tissue confirming the presence of an IDH1 R132 variant; AND Patient must have had systemic therapy for this condition prior to initiating treatment with this drug for this condition; AND Patient must have/have had a WHO performance status of 2 or less at treatment initiation with this drug; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Confirm that evidence of the presence of a pathogenic variant of the IDH1 gene is documented/retained in the patient's medical records once only with the first PBS prescription.	Compliance with Authority Required procedures - Streamlined Authority Code 16701
C16709	P16709	CN16709	Etanercept	Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; or Patient must have received prior PBS-subsidised treatment with a biological medicine	Compliance with Written Authority Required procedures

	under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a 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 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). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the

				patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	
C16710	P16710	CN16710	Etanercept	Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or The condition must have a C-reactive protein (CRP) level greater than 15 mg per L;	Compliance with Written Authority Required procedures

	AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Major joints are defined as (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). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this

				restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
C16713	P16713	CN16713	Etanercept	Ankylosing spondylitis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application; AND Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; or Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; or Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be provided at the time of application and documented in the patient's medical records:	Compliance with Written Authority Required procedures

				(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline ESR and/or CRP level. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C16716	P16716	CN16716	Etanercept	Severe chronic plaque psoriasis Initial treatment - Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application.	Compliance with Written Authority Required procedures

				The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C16717	P16717	CN16717	Etanercept	Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior	Compliance with Written Authority Required procedures

	to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

C16718	P16718	CN16718	Etanercept	Severe active juvenile idiopathic arthritis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated 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 at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a 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) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following 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, cervical spine 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). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment	Compliance with Written Authority Required procedures

				of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.	
C16720	P16720	CN16720	Etanercept	Severe chronic plaque psoriasis Subsequent continuing treatment, whole body Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in	Compliance with Authority Required procedures - Streamlined Authority Code 16720

				the patient's medical notes. Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16725	P16725	CN16725	Etanercept	Severe active rheumatoid arthritis First continuing treatment Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a 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 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). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be	Compliance with Written Authority Required procedures

				used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
C16727	P16727	CN16727	Etanercept	Severe active juvenile idiopathic arthritis Initial treatment - Initial 1 (new patient) Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose	Compliance with Written Authority Required procedures

	of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application. The following 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: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine 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 joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application. 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) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C16728	P16728	CN16728	Etanercept	Severe active juvenile idiopathic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; or Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater	Compliance with Written Authority Required procedures

	than 25 mm per hour; or The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Active joints are defined as: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine 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). All measurements must be no more than 4 weeks old at the time of this application. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

C16735	P16735	CN16735	Maribavir	Cytomegalovirus infection and disease Patient must have received a hematopoietic stem-cell transplant; OR Patient must have received a solid-organ transplant; AND Patient must have a cytomegalovirus infection or cytomegalovirus disease that is resistant, refractory or intolerant/contraindicated to appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet; OR Patient must have received and is intolerant to continued use of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet; AND The treatment must be used as monotherapy for this condition under this restriction; AND Patient must not have previously demonstrated resistance to this drug; AND Patient must not have cytomegalovirus disease that involves the central nervous system; AND Patient must not have cytomegalovirus retinitis. For the purpose of administering this restriction: (i) A patient is determined to be refractory if after at least two weeks of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet, they fail to achieve a greater than 1log10 decrease in cytomegalovirus DNA level. (ii) A patient is determined to be resistant by the identification of a genetic alteration that decreases susceptibility to ganciclovir, valganciclovir, cidofovir or foscarnet. (iii) A patient with Grade 3 neutropenia (an absolute neutrophil count less than 1000 cells per cubic millimetre) or impaired renal function (creatinine clearance less than 50 mL/min) is determined to be intolerant/contraindicated.	Compliance with Authority Required procedures - Streamlined Authority Code 16735
C16737	P16737	CN16737	Etanercept	Severe psoriatic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND	Compliance with Written Authority Required procedures

	The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Major joints are defined as (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). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. 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. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be

				eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C16743	P16743	CN16743	Etanercept	Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin 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. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.	Compliance with Written Authority Required procedures

				(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C16747	P16747	CN16747	Etanercept	Ankylosing spondylitis Initial treatment - Initial 1 (new patient) The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the	Compliance with Written Authority Required procedures

	lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	

				The following must be provided at the time of application and documented in the patient's medical records: (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) baseline ESR and/or CRP level. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C16748	P16748	CN16748	Etanercept	Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Patient must not have received PBS-subsidised treatment with a biological medicine 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 at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. 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.	Compliance with Written Authority Required procedures

				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: (a) details of the proposed prescription(s); and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C16750	P16750	CN16750	Etanercept	Severe chronic plaque psoriasis Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply Patient must have received insufficient therapy with this drug under the first continuing	Compliance with Authority Required procedures

				treatment, Whole body restriction to complete 24 weeks treatment; or Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; or Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; or Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot 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 restrictions; AND The treatment must be as systemic monotherapy (other than methotrexate). Patient must be at least 18 years of age. Must be treated by a dermatologist.	
C16753	P16753	CN16753	Etanercept	Severe chronic plaque psoriasis First continuing treatment, Face, hand, foot Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.	Compliance with Written Authority Required procedures

				The most recent PASI assessment must be no more than 1 month old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16754	P16754	CN16754	Etanercept	Severe psoriatic arthritis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. 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	Compliance with Written Authority Required procedures

				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 used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug within this treatment cycle, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16755	P16755	CN16755	Nivolumab	Unresectable or metastatic urothelial carcinoma Continuing treatment Patient must have previously received up to a maximum 6 doses of combined therapy with both: (i) nivolumab, (ii) cisplatin and gemcitabine, as initial treatment for this	Compliance with Authority Required procedures - Streamlined Authority Code 16755

				condition; AND The treatment must be as monotherapy for this condition. Patient must be undergoing treatment with a dosing regimen as set out in the drug's Therapeutic Goods Administration (TGA) approved Product Information; AND Patient must not be undergoing continuing PBS-subsidised treatment where this prescription extends treatment beyond whichever comes first: (i) 24 months from treatment initiation, irrespective of whether initial treatment was PBS-subsidised/non-PBS-subsidised, (ii) disease progression despite treatment with this drug, (iii) unacceptable toxicity; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.	
C16757	P16757	CN16757	Olaparib	Early breast cancer Continuing treatment Patient must have received PBS-subsidised treatment with this drug as adjuvant therapy for this condition; AND Patient must not have developed disease recurrence while receiving treatment with this drug for this condition; AND The treatment must not be a PBS-subsidised benefit beyond a total of 52 weeks of treatment (including any non-PBS-subsidised supply); AND The treatment must not in combination with any of the following: (i) abemaciclib, (ii) pembrolizumab, (iii) ribociclib.	Compliance with Authority Required procedures
C16761	P16761	CN16761	Etanercept	Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction.	Compliance with Written Authority Required procedures

	Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin 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. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

				It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C16763	P16763	CN16763	Etanercept	Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or	Compliance with Authority Required procedures

				Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must be as systemic monotherapy (other than methotrexate); 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 dermatologist.	
C16764	P16764	CN16764	Etanercept	Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. 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 authority application must be made in writing and must include: (a) details of the proposed prescription(s); and	Compliance with Written Authority Required procedures

				(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16765	P16765	CN16765	Etanercept	Ankylosing spondylitis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.	Compliance with Written Authority Required procedures

				The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16766	P16766	CN16766	Etanercept	Severe chronic plaque psoriasis Subsequent continuing treatment, whole body Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND	Compliance with Written Authority Required procedures

				Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16771	P16771	CN16771	Abemaciclib	Early breast cancer The treatment must be adjuvant to surgical resection; AND Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; or Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal;	Compliance with Authority Required procedures

				AND The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing this drug; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be hormone receptor positive; AND The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system); AND The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 2 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression; AND The treatment must not be in combination with any of the following: (i) olaparib, (ii) pembrolizumab, (iii) ribociclib. Patient must be undergoing concurrent treatment with endocrine therapy where this drug is being prescribed as a PBS benefit. Retain all pathology imaging and investigative test results in the patient's medical records. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C16772	P16772	CN16772	Etanercept	Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level,	Compliance with Written Authority Required procedures

				as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16773	P16773	CN16773	Etanercept	Ankylosing spondylitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND	Compliance with Written Authority Required procedures

	Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

				within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16774	P16774	CN16774	Etanercept	Severe psoriatic arthritis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. 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 used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed authority application form relevant to the indication and treatment	Compliance with Written Authority Required procedures

				phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16775	P16775	CN16775	Etanercept	Severe active juvenile idiopathic arthritis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated 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 at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a 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) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from	Compliance with Written Authority Required procedures

	baseline; or (c) a reduction in the number of the following 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, cervical spine 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). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

C16777	P16777	CN16777	Etanercept	Severe active juvenile idiopathic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years; AND Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a 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) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following 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, cervical spine 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 authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.	Compliance with Written Authority Required procedures

				To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
C16778	P16778	CN16778	Etanercept	Severe psoriatic arthritis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-	Compliance with Authority Required procedures - Streamlined Authority Code 16778

				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 used to determine response for all subsequent continuing treatments. The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16779	P16779	CN16779	Etanercept	Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist.	Compliance with Written Authority Required procedures

				The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C16780	P16780	CN16780	Olaparib	Early breast cancer Initial treatment The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND Patient must have received neoadjuvant or adjuvant chemotherapy; AND The treatment must be adjuvant to surgical resection; AND The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene variant; AND Patient must have received neoadjuvant chemotherapy, and residual invasive cancer is confirmed in the breast and/or resected lymph nodes (pathological complete response was not achieved); or Patient must have received adjuvant chemotherapy for triple negative breast cancer, and has either: (a) node positive disease is present, (b) a primary tumour greater than 20 mm; or Patient must have received adjuvant chemotherapy for hormone receptor positive breast cancer, and has at least 4 positive lymph nodes; AND The treatment must not be a PBS-subsidised benefit beyond the following, whichever	Compliance with Authority Required procedures

				comes first: (i) a total of 52 weeks of treatment (including any non-PBS-subsidised supply), (ii) disease recurrence. Mark any remaining repeat prescriptions with the word 'cancelled' where (i)/(ii) has occurred; AND The treatment must be commenced within 12 weeks of completing other therapy noting that other therapy can be any of the following therapy: (i) surgery, (ii) radiotherapy, (iii) chemotherapy; AND The treatment must not in combination with any of the following: (i) abemaciclib, (ii) pembrolizumab, (iii) ribociclib. Retain all pathology imaging and investigative test results in the patient's medical records. Treatment with this drug for this condition is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under metastatic disease is no longer available).	
C16785	P16785	CN16785	Etanercept	Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine 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 medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological	Compliance with Written Authority Required procedures

				medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16787	P16787	CN16787	Etanercept	Severe active juvenile idiopathic arthritis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated 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 at least 18 years of age. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L	Compliance with Authority Required procedures - Streamlined Authority Code 16787

				or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following 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, cervical spine 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). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.	
C16788	P16788	CN16788	Etanercept	Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of	Compliance with Written Authority Required procedures

	rheumatoid arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; or Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; or Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application; AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2

DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment 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 and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total 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).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

				If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	
C16789	P16789	CN16789	Etanercept	Ankylosing spondylitis Subsequent continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; or Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following: (a) an ESR measurement no greater than 25 mm per hour; or (b) a CRP measurement no greater than 10 mg per L; or (c) an ESR or CRP measurement reduced by at least 20% from baseline. Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment. The assessment of response to treatment must be documented in the patient's medical records. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.	Compliance with Written Authority Required procedures

				Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16790	P16790	CN16790	Nivolumab	Unresectable or metastatic urothelial carcinoma Initial treatment The condition must not have previously been treated with PBS-subsidised systemic therapy for unresectable or metastatic urothelial carcinoma; AND The treatment must be initiated in combination with cisplatin and gemcitabine; AND Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND Patient must not have received prior treatment with a PBS-subsidised programmed cell death-1 (PD-1) inhibitor or programmed cell death ligand-1 (PD-L1) inhibitor for this condition. Patient must be undergoing treatment with a dosing regimen as set out in the drug's Therapeutic Goods Administration (TGA) approved Product Information. Patient must only receive up to a maximum 6 doses of PBS-subsidised combined therapy with both: (i) nivolumab, (ii) cisplatin and gemcitabine, under this PBS listing, once in a lifetime.	Compliance with Authority Required procedures - Streamlined Authority Code 16790
C16792	P16792	CN16792	Etanercept	Severe chronic plaque psoriasis First continuing treatment, Whole body Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist.	Compliance with Written Authority Required procedures

				An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16795	P16795	CN16795	Etanercept	Severe chronic plaque psoriasis Subsequent continuing treatment, face, hand, foot Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to their most recent course of treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing	Compliance with Authority Required procedures - Streamlined Authority Code 16795

				treatment course authorised under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16806	P16806	CN16806	Maribavir	Cytomegalovirus infection and disease Patient must have received a hematopoietic stem-cell transplant; OR Patient must have received a solid-organ transplant; AND Patient must have a cytomegalovirus infection or cytomegalovirus disease that is resistant, refractory or intolerant/contraindicated to appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet; OR Patient must have received and is intolerant to continued use of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet; AND The treatment must be used as monotherapy for this condition under this restriction; AND Patient must not have previously demonstrated resistance to this drug; AND Patient must not have cytomegalovirus disease that involves the central nervous system; AND Patient must not have cytomegalovirus retinitis.	Compliance with Authority Required procedures - Streamlined Authority Code 16806

				For the purpose of administering this restriction: (i) A patient is determined to be refractory if after at least two weeks of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet, they fail to achieve a greater than 1log10 decrease in cytomegalovirus DNA level. (ii) A patient is determined to be resistant by the identification of a genetic alteration that decreases susceptibility to ganciclovir, valganciclovir, cidofovir or foscarnet. (iii) A patient with Grade 3 neutropenia (an absolute neutrophil count less than 1000 cells per cubic millimetre) or impaired renal function (creatinine clearance less than 50 mL/min) is determined to be intolerant/contraindicated.	
C16808	P16808	CN16808	Ribociclib	Early breast cancer The treatment must be adjuvant to surgical resection; AND Patient must have been untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy at the time non-PBS-subsidised or PBS-subsidised treatment was initiated; or Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing this drug; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be hormone receptor positive; AND The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system); AND The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 3 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression; AND The treatment must not be in combination with any of the following: (i) abemaciclib, (ii) olaparib, (iii) pembrolizumab. Patient must be undergoing concurrent treatment with a non-steroidal aromatase inhibitor where this drug is being prescribed as a PBS benefit. Retain all pathology imaging and investigative test results in the patient's medical records. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Compliance with Authority Required procedures

C16809	P16809	CN16809	Ribociclib	Early breast cancer The treatment must be adjuvant to surgical resection; AND Patient must have been untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy at the time non-PBS-subsidised or PBS-subsidised treatment was initiated; or Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing this drug; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be hormone receptor positive; AND The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system); AND The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 3 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression; AND The treatment must not be in combination with any of the following: (i) abemaciclib, (ii) olaparib, (iii) pembrolizumab; AND Patient must require dosage reduction requiring a pack of 21 tablets. Patient must be undergoing concurrent treatment with a non-steroidal aromatase inhibitor where this drug is being prescribed as a PBS benefit. Retain all pathology imaging and investigative test results in the patient's medical records. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	Compliance with Authority Required procedures

[143] Schedule 4, Part 2, after entry for Variation Code "V16000"

insert:

V16755	Nivolumab	An increase in repeat prescriptions, up to a value of 11, may only be sought where the prescribed dosing is 240 mg administered fortnightly.

[144] Schedule 5, entry for Allopurinol *[GRP-15579]*

omit from the column headed "Brand": Allopurinol APOTEX

[145] Schedule 5, entry for Amlodipine *[GRP-19712]*

omit from the column headed "Brand": Amlodipine APOTEX

[146] Schedule 5, entry for Amoxicillin *[GRP-26767]*

omit from the column headed "Brand": Cilamox

[147] Schedule 5, after entry for Aripiprazole *[GRP-20910]*

insert:

Aripiprazole	GRP-29792	Powder for injection 400 mg (as monohydrate) with diluent	Injection	Abilify Maintena ARIPENA

[148] Schedule 5, entry for Azithromycin

substitute:

Azithromycin	GRP-29796	Tablet 500 mg (as dihydrate)	Oral	APO-Azithromycin Azithromycin Sandoz Azithromycin Viatris AZITHROMYCIN-WGR ZITHRO Zithromax
Azithromycin	GRP-29796	Tablet 500 mg (as dihydrate) (S19A)	Oral	Azithromycin Tablets, USP 500 mg (Precision Dose, USA)

[149] Schedule 5, omit entry for Bivalirudin

[150] Schedule 5, entry for Bosentan *[GRP-21635]*

omit from the column headed "Brand": Bosentan Mylan

[151] Schedule 5, entry for Cefaclor *[GRP-19974]*

omit from the column headed "Brand": Karlor CD

[152] Schedule 5, entry for Cefaclor *[GRP-20159]*

omit from the column headed "Brand": Aclor 125

[153] Schedule 5, entry for Cefaclor *[GRP-20181]*

omit from the column headed "Brand": Aclor 250

[154] Schedule 5, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4

insert in alphabetical order in the column headed "Brand": Nepexto

[155] Schedule 5, entries for Ezetimibe

omit:

Ezetimibe	GRP-29270	Tablet 10 mg (S19A)	Oral	Ezetimibe USP (Camber, USA)

[156] Schedule 5, entry for Ezetimibe with simvastatin *[GRP-22376]*

omit from the column headed "Brand": Zeklen 10/40 mg

[157] Schedule 5, entry for Ezetimibe with simvastatin *[GRP-22381]*

omit from the column headed "Brand": Zeklen 10/10 mg

[158] Schedule 5, entry for Ezetimibe with simvastatin *[GRP-22383]*

omit from the column headed "Brand": Zeklen 10/20 mg

[159] Schedule 5, entry for Ezetimibe with simvastatin *[GRP-22393]*

omit from the column headed "Brand": Zeklen 10/80 mg

[160] Schedule 5, entries for Felodipine

omit from the column headed "Brand" (all instances): Fendex ER

[161] Schedule 5, entry for Fingolimod

insert in the column headed "Brand" after entry for the Brand "AKM Fingolimod": FILOSIR

[162] Schedule 5, entry for Gliclazide *[GRP-19637]*

omit from the column headed "Brand": Glyade MR

[163] Schedule 5, entries for Glimepiride

omit from the column headed "Brand" (all instances): Glimepiride APOTEX

[164] Schedule 5, omit entry for Hypromellose with carbomer 980

[165] Schedule 5, entry for Imiquimod in the form Cream 50 mg per g, 250 mg single use sachets, 12

omit from the column headed "Brand": Aldiq

[166] Schedule 5, omit entries for Ipratropium

[167] Schedule 5, entries for Leflunomide

omit from the column headed "Brand" (all instances): Leflunomide APOTEX

[168] Schedule 5, entry for Lercanidipine *[GRP-19911]*

omit from the column headed "Brand": Lercanidipine APOTEX

[169] Schedule 5, entry for Letrozole

omit from the column headed "Brand": Letrozole APOTEX

[170] Schedule 5, entry for Levetiracetam *[GRP-19643]*

omit from the column headed "Brand": Kevtam 500

[171] Schedule 5, entry for Levetiracetam *[GRP-19648]*

(a) omit from the column headed "Brand": Kevtam 250

(b) omit from the column headed "Brand": Levetiracetam Mylan

[172] Schedule 5, entry for Levetiracetam *[GRP-19680]*

(a) omit from the column headed "Brand": Kevtam 1000

(b) omit from the column headed "Brand": Levetiracetam Mylan

[173] Schedule 5, entries for Lurasidone

omit from the column headed "Brand" (all instances): Latuda

[174] Schedule 5, entry for Methenamine

(a) insert in the column headed "Brand" as first entry: APOHEALTH Urinary Tract Antibacterial

(b) insert in the column headed "Brand" after entry for the Brand "APOHEALTH Urinary Tract Antibacterial": Chemists' Own Urinary Tract Antibacterial

[175] Schedule 5, entries for Methylphenidate

omit:

Methylphenidate	GRP-25859	Tablet containing methylphenidate hydrochloride 27 mg (extended release)	Oral	Concerta METHYLPHENIDATE-TEVA XR Methylphenidate XR ARX

Methylphenidate	GRP-25885	Tablet containing methylphenidate hydrochloride 18 mg (extended release)	Oral	Concerta METHYLPHENIDATE-TEVA XR Methylphenidate XR ARX
Methylphenidate	GRP-25891	Tablet containing methylphenidate hydrochloride 36 mg (extended release)	Oral	Concerta METHYLPHENIDATE-TEVA XR Methylphenidate XR ARX
Methylphenidate	GRP-25892	Tablet containing methylphenidate hydrochloride 54 mg (extended release)	Oral	Concerta METHYLPHENIDATE-TEVA XR Methylphenidate XR ARX

[176] Schedule 5, after entry for Methylphenidate *[GRP-27215]*

insert:

Methylphenidate	GRP-29788	Tablet containing methylphenidate hydrochloride 54 mg (extended release)	Oral	Concerta METHYLPHENIDATE-TEVA XR Methylphenidate XR ARX
Methylphenidate	GRP-29788	Tablet containing methylphenidate hydrochloride 54 mg (extended release) (S19A)	Oral	Concerta (Switzerland)
Methylphenidate	GRP-29788	Tablet containing methylphenidate hydrochloride 54 mg (extended release) Concerta (Switzerland) (S19A)	Oral	Concerta (Switzerland)
Methylphenidate	GRP-29789	Tablet containing methylphenidate hydrochloride 36 mg (extended release)	Oral	Concerta METHYLPHENIDATE-TEVA XR Methylphenidate XR ARX
Methylphenidate	GRP-29789	Tablet containing methylphenidate hydrochloride 36 mg (extended release) (S19A)	Oral	Concerta (Switzerland)
Methylphenidate	GRP-29789	Tablet containing methylphenidate hydrochloride 36 mg (extended release) Concerta (Switzerland) (S19A)	Oral	Concerta (Switzerland)
Methylphenidate	GRP-29797	Tablet containing methylphenidate hydrochloride 27 mg (extended release)	Oral	Concerta METHYLPHENIDATE-TEVA XR Methylphenidate XR ARX
Methylphenidate	GRP-29797	Tablet containing methylphenidate hydrochloride 27 mg (extended release) (S19A)	Oral	Concerta (Switzerland)
Methylphenidate	GRP-29799	Tablet containing methylphenidate hydrochloride 18 mg (extended release)	Oral	Concerta

				METHYLPHENIDATE-TEVA XR Methylphenidate XR ARX
Methylphenidate	GRP-29799	Tablet containing methylphenidate hydrochloride 18 mg (extended release) (S19A)	Oral	Concerta (Switzerland)
Methylphenidate	GRP-29799	Tablet containing methylphenidate hydrochloride 18 mg (extended release) Concerta (Switzerland) (S19A)	Oral	Concerta (Switzerland)

[177] Schedule 5, entries for Morphine in each of the forms: Tablet containing morphine sulfate pentahydrate 60 mg (controlled release); Tablet containing morphine sulfate pentahydrate 100 mg (controlled release); Tablet containing morphine sulfate pentahydrate 10 mg (controlled release); and Tablet containing morphine sulfate pentahydrate 30 mg (controlled release)

omit from the column headed "Brand": Morphine MR Mylan

[178] Schedule 5, after entry for Naproxen *[GRP-20009]*

insert:

Naproxen	GRP-29794	Oral suspension 125 mg per 5 mL, 474 mL	Oral	Phebra Naproxen Suspension
Naproxen	GRP-29794	Oral suspension 125 mg per 5 mL, 474 mL (S19A)	Oral	Pediapharm Naproxen Suspension 25 mg/mL (Medexus Pharma, Canada)

[179] Schedule 5, entry for Norfloxacin

omit from the column headed "Brand": Nufloxib

[180] Schedule 5, entry for Olanzapine *[GRP-15492]*

omit from the column headed "Brand": Olanzapine APOTEX

[181] Schedule 5, entry for Pantoprazole *[GRP-20087]*

omit from the column headed "Brand": Pantoprazole APOTEX

[182] Schedule 5, entry for Rivaroxaban *[GRP-29154]*

insert in the column headed "Brand" as first entry: APO-Rivaroxaban

[183] Schedule 5, entries for Rivaroxaban in each of the forms: Tablet 20 mg; Tablet 10 mg; and Tablet 15 mg

(a) insert in the column headed "Brand" as first entry: APO-Rivaroxaban

(b) insert in the column headed "Brand" after entry for the Brand "iXarola": Rivarelto

[184] Schedule 5, entries for Rosuvastatin

substitute:

Rosuvastatin	GRP-19557	Tablet 20 mg (as calcium)	Oral	APO-ROSUVASTATIN APX-Rosuvastatin Blooms Rosuvastatin Cavstat Crestor Crosuva 20 Pharmacor Rosuvastatin 20 Rosuvastatin Lupin Rosuvastatin RBX Rosuvastatin Sandoz ROSUVASTATIN-WGR
Rosuvastatin	GRP-19558	Tablet 10 mg (as calcium)	Oral	APO-ROSUVASTATIN APX-Rosuvastatin Blooms Rosuvastatin Cavstat Crestor Crosuva 10 Pharmacor Rosuvastatin 10 Rosuvastatin Lupin Rosuvastatin RBX Rosuvastatin Sandoz ROSUVASTATIN-WGR
Rosuvastatin	GRP-19562	Tablet 40 mg (as calcium)	Oral	APO-ROSUVASTATIN APX-Rosuvastatin Blooms Rosuvastatin Cavstat Crestor Crosuva 40 Pharmacor Rosuvastatin 40 Rosuvastatin Lupin Rosuvastatin RBX Rosuvastatin Sandoz ROSUVASTATIN-WGR
Rosuvastatin	GRP-19569	Tablet 5 mg (as calcium)	Oral	APO-ROSUVASTATIN APX-Rosuvastatin Blooms Rosuvastatin

				Cavstat Crestor Crosuva 5 Pharmacor Rosuvastatin 5 Rosuvastatin APOTEX Rosuvastatin Lupin Rosuvastatin RBX Rosuvastatin Sandoz ROSUVASTATIN-WGR

[185] Schedule 5, entries for Sacubitril with valsartan in each of the forms: Tablet containing sacubitril 24.3 mg with valsartan 25.7 mg; Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg; and Tablet containing sacubitril 48.6 mg with valsartan 51.4 mg

(a) insert in the column headed "Brand" after entry for the Brand "Entresto": Omtralo

(b) insert in the column headed "Brand" after entry for the Brand "Pharmacor Sacubitril/Valsartan": Sacubitril/Valsartan Alphapharm

[186] Schedule 5, entry for Sevelamer in the form Tablet containing sevelamer carbonate 800 mg

omit from the column headed "Brand": Sevelamer Apotex

[187] Schedule 5, entry for Sumatriptan in the form Tablet 50 mg (as succinate)

omit from the column headed "Brand": IMIGRAN MIGRAINE