PB 52 of 2024

National Health (Listing of Pharmaceutical Benefits) Amendment (June Update) Instrument 2024

National Health Act 1953

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

Dated 30 May 2024

NIKOLAI TSYGANOV
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 (June Update) Instrument 2024*.

(2) This Instrument may also be cited as PB 52 of 2024.

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 June 2024*	*1 June 2024*

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Brands: Adalicip; Humira; and Yuflyma; Maximum Quantity: 6; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C12275 C12336**

(b) *insert in numerical order in the column headed "Circumstances":* **C15249 C15309 C15319**

(c) *omit from the column headed "Purposes":* **P12275 P12336**

(d) *insert in numerical order in the column headed "Purposes":* **P15249 P15309 P15319**

[2] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brands: Amgevita; Hadlima; Hyrimoz; and Idacio; Maximum Quantity: 6; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C12275 C12336**

(b) *insert in numerical order in the column headed "Circumstances":* **C15249 C15309 C15319**

(c) *omit from the column headed "Purposes":* **P12275 P12336**

(d) *insert in numerical order in the column headed "Purposes":* **P15249 P15309 P15319**

[3] **Schedule 1, Part 1, entry for Adalimumab in each of the forms: Injection 80 mg in 0.8 mL pre-filled pen; and Injection 80 mg in 0.8 mL pre-filled syringe *[Maximum Quantity: 3; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C12275 C12278**

(b) *insert in numerical order in the column headed "Circumstances":* **C15249 C15309 C15319**

(c) *omit from the column headed "Purposes":* **P12275 P12278**

(d) *insert in numerical order in the column headed "Purposes":* **P15249 P15309 P15319**

[4] **Schedule 1, Part 1, entry for Alogliptin in the form Tablet 6.25 mg (as benzoate) *[Maximum Quantity: 28; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C4349** *substitute:* **C15261**

(b) *omit from the column headed "Purposes":* **P4349** *substitute:* **P15261**

[5] **Schedule 1, Part 1, entry for Alogliptin in the form Tablet 6.25 mg (as benzoate) *[Maximum Quantity: 56; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C14862** *substitute:* **C15287**

(b) *omit from the column headed "Purposes":* **P14862** *substitute:* **P15287**

[6] **Schedule 1, Part 1, entry for Alogliptin in the form Tablet 12.5 mg (as benzoate) *[Maximum Quantity: 28; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C4349** *substitute:* **C15261**

(b) *omit from the column headed "Purposes":* **P4349** *substitute:* **P15261**

[7] **Schedule 1, Part 1, entry for Alogliptin in the form Tablet 12.5 mg (as benzoate) *[Maximum Quantity: 56; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C14862** *substitute:* **C15287**

(b) *omit from the column headed "Purposes":* **P14862** *substitute:* **P15287**

[8] **Schedule 1, Part 1, entry for Alogliptin in the form Tablet 25 mg (as benzoate) *[Maximum Quantity: 28; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C4349** *substitute:* **C15261**

(b) *omit from the column headed "Purposes":* **P4349** *substitute:* **P15261**

[9] **Schedule 1, Part 1, entry for Alogliptin in the form Tablet 25 mg (as benzoate) *[Maximum Quantity: 56; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C14862** *substitute:* **C15287**

(b) *omit from the column headed "Purposes":* **P14862** *substitute:* **P15287**

[10] **Schedule 1, Part 1, entry for Alogliptin with metformin in the form Tablet containing 12.5 mg alogliptin (as benzoate) with 1 g metformin hydrochloride *[Maximum Quantity: 56; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C4423 C4427** *substitute:* **C15276**

(b) *omit from the column headed "Purposes":* **P4423 P4427** *substitute:* **P15276**

[11] **Schedule 1, Part 1, entry for Alogliptin with metformin in the form Tablet containing 12.5 mg alogliptin (as benzoate) with 1 g metformin hydrochloride *[Maximum Quantity: 112; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C14876** *substitute:* **C15288**

(b) *omit from the column headed "Purposes":* **P14876** *substitute:* **P15288**

[12] **Schedule 1, Part 1, entry for Alogliptin with metformin in the form Tablet containing 12.5 mg alogliptin (as benzoate) with 500 mg metformin hydrochloride *[Maximum Quantity: 56; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C4423 C4427** *substitute:* **C15276**

(b) *omit from the column headed "Purposes":* **P4423 P4427** *substitute:* **P15276**

[13] **Schedule 1, Part 1, entry for Alogliptin with metformin in the form Tablet containing 12.5 mg alogliptin (as benzoate) with 500 mg metformin hydrochloride *[Maximum Quantity: 112; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C14876** *substitute:* **C15288**

(b) *omit from the column headed "Purposes":* **P14876** *substitute:* **P15288**

[14] **Schedule 1, Part 1, entry for Alogliptin with metformin in the form Tablet containing 12.5 mg alogliptin (as benzoate) with 850 mg metformin hydrochloride *[Maximum Quantity: 56; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C4423 C4427** *substitute:* **C15276**

(b) *omit from the column headed "Purposes":* **P4423 P4427** *substitute:* **P15276**

[15] **Schedule 1, Part 1, entry for Alogliptin with metformin in the form Tablet containing 12.5 mg alogliptin (as benzoate) with 850 mg metformin hydrochloride *[Maximum Quantity: 112; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C14876** *substitute:* **C15288**

(b) *omit from the column headed "Purposes":* **P14876** *substitute:* **P15288**

[16] **Schedule 1, Part 1, entry for Ambrisentan in the form Tablet 5 mg**

omit:

Ambrisentan	Tablet 5 mg	Oral	Ambrisentan Mylan	AF	MP	See Note 3	See Note 3	See Note 3	See Note 3	30	D(100)

[17] **Schedule 1, Part 1, entry for Anastrozole**

omit:

Anastrozole	Tablet 1 mg	Oral	Arimidex	AP	MP NP	C5464	P5464	30	5	30
Anastrozole	Tablet 1 mg	Oral	Arimidex	AP	MP NP	C14943	P14943	60	5	30

[18] Schedule 1, Part 1, entry for Apremilast in each of the forms: Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg; and Tablet 30 mg

omit from the column headed "Circumstances": **C14417** *substitute:* **C15326**

[19] Schedule 1, Part 1, entry for Azacitidine

substitute:

Azacitidine	Powder for injection 100 mg	Injection	Azacitidine Accord	OC	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
Azacitidine	Powder for injection 100 mg	Injection	Azacitidine Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
Azacitidine	Powder for injection 100 mg	Injection	AZACITIDINE EUGIA	YG	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
Azacitidine	Powder for injection 100 mg	Injection	Azacitidine Juno	JO	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
Azacitidine	Powder for injection 100 mg	Injection	Azacitidine MSN	JU	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
Azacitidine	Powder for injection 100 mg	Injection	Azacitidine Sandoz	SZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
Azacitidine	Powder for injection 100 mg	Injection	Azacitidine-Teva	TB	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
Azacitidine	Tablet 200 mg	Oral	Onureg	CJ	MP	C14338		14	2	7	
Azacitidine	Tablet 300 mg	Oral	Onureg	CJ	MP	C14332 C14338	P14332 P14338	14	2	7	
Azacitidine	Tablet 300 mg	Oral	Onureg	CJ	MP	C14323	P14323	21	1	7	

[20] Schedule 1, Part 1, entry for Benzathine benzylpenicillin

substitute:

Benzathine benzylpenicillin	Injection containing 1,200,000 units benzathine benzylpenicillin tetrahydrate in 2.3 mL single use pre-filled	Injection	Bicillin L-A	PF	PDP MP NP			10	0	10	

	syringe									
Benzathine benzylpenicillin	Injection containing 600,000 units benzathine benzylpenicillin tetrahydrate in 1.17 mL single use pre-filled syringe	Injection	Bicillin L-A	PF	PDP MP NP		10	0	10	
Benzathine benzylpenicillin	Powder for injection 1,200,000 units with diluent 5 mL (S19A)	Injection	Benzylpenicillin Benzathine (Brancaster Pharma, UK)	OJ	PDP MP NP		10	0	1	
Benzathine benzylpenicillin	Powder for injection 1,200,000 units with diluent 5 mL (S19A)	Injection	Extencilline Benzathine Benzylpenicillin (France)	YO	PDP MP NP		10	0	1	

[21] Schedule 1, Part 1, entry for Bisacodyl

omit:

Bisacodyl	Enemas 10 mg in 5 mL, 25	Rectal	Bisalax	OX	MP NP	C5613 C5640 C5685 C5720 C5775 C5776 C5804	1	2	1	

[22] Schedule 1, Part 1, entry for Bortezomib in the form Powder for injection 1 mg

omit:

Bortezomib	Powder for injection 1 mg	Injection	Velcade	JC	MP	C11099 C13745	See Note 3	See Note 3	1	D(100)

[23] Schedule 1, Part 1, entry for Bortezomib in the form Powder for injection 3 mg

omit:

Bortezomib	Powder for injection 3 mg	Injection	Velcade	JC	MP	C11099 C13745	See Note 3	See Note 3	1	D(100)

[24] Schedule 1, Part 1, entry for Bortezomib in the form Powder for injection 3.5 mg

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

Bortezomib	Powder for injection 3.5 mg	Injection	BORTEZOMIB EUGIA	YG	MP	C11099 C13745		See Note 3	See Note 3	1	D(100)

(b) *omit:*

Bortezomib	Powder for injection 3.5 mg	Injection	Velcade	JC	MP	C11099 C13745		See Note 3	See Note 3	1	D(100)

[25] Schedule 1, Part 1, entry for Bosentan

substitute:

Bosentan	Tablet 62.5 mg (as monohydrate)	Oral	Bosentan APO	GX	MP	See Note 3	See Note 3	See Note 3	See Note 3	60	D(100)
Bosentan	Tablet 62.5 mg (as monohydrate)	Oral	BOSENTAN DR.REDDY'S	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	60	D(100)
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)
Bosentan	Tablet 62.5 mg (as monohydrate)	Oral	Bosentan RBX	RA	MP	See Note 3	See Note 3	See Note 3	See Note 3	60	D(100)
Bosentan	Tablet 62.5 mg (as monohydrate)	Oral	BOSLEER	RW	MP	See Note 3	See Note 3	See Note 3	See Note 3	60	D(100)
Bosentan	Tablet 125 mg (as monohydrate)	Oral	Bosentan APO	GX	MP	See Note 3	See Note 3	See Note 3	See Note 3	60	D(100)
Bosentan	Tablet 125 mg (as monohydrate)	Oral	Bosentan Cipla	LR	MP	See Note 3	See Note 3	See Note 3	See Note 3	60	D(100)
Bosentan	Tablet 125 mg (as monohydrate)	Oral	BOSENTAN DR.REDDY'S	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	60	D(100)
Bosentan	Tablet 125 mg (as monohydrate)	Oral	Bosentan GH	GQ	MP	See Note 3	See Note 3	See Note 3	See Note 3	60	D(100)
Bosentan	Tablet 125 mg (as monohydrate)	Oral	Bosentan Mylan	AF	MP	See Note 3	See Note 3	See Note 3	See Note 3	60	D(100)
Bosentan	Tablet 125 mg (as monohydrate)	Oral	Bosentan RBX	RA	MP	See Note 3	See Note 3	See Note 3	See Note 3	60	D(100)

Bosentan	Tablet 125 mg (as monohydrate)	Oral	BOSLEER	RW	MP	See Note 3	See Note 3	See Note 3	See Note 3	60	D(100)

[26] Schedule 1, Part 1, entry for Budesonide with formoterol

substitute:

Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 100 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Symbicort Turbuhaler 100/6	AP	MP	C10538		1	5	1	
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 100 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Symbicort Turbuhaler 100/6	AP	MP NP	C4380		1	5	1	
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses	Inhalation by mouth	Bufomix Easyhaler 200/6	OX	MP NP	C10464	P10464	2	2	1	
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 60 doses	Inhalation by mouth	Bufomix Easyhaler 200/6	OX	MP NP	C7970	P7970	2	5	1	
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate	Inhalation by mouth	Bufomix Easyhaler 200/6	OX	MP	C10538	P10538	2	5	1	

	dihydrate 6 micrograms per dose, 60 doses									
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	BiResp Spiromax	TB	MP NP	C10464	P10464	1	2	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	BiResp Spiromax	TB	MP NP	C7970	P7970	1	5	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	BiResp Spiromax	TB	MP	C10538	P10538	1	5	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	DuoResp Spiromax	EV	MP NP	C10464	P10464	1	2	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	DuoResp Spiromax	EV	MP NP	C7970	P7970	1	5	1
Budesonide	Powder for oral inhalation in	Inhalation	DuoResp Spiromax	EV	MP	C10538	P10538	1	5	1

with formoterol	breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	by mouth								
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Rilast TURBUHALER 200/6	XT	MP NP	C10464	P10464	1	2	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Rilast TURBUHALER 200/6	XT	MP NP	C7970	P7970	1	5	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Rilast TURBUHALER 200/6	XT	MP	C10538	P10538	1	5	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Symbicort Turbuhaler 200/6	AP	MP NP	C10464	P10464	1	2	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate	Inhalation by mouth	Symbicort Turbuhaler 200/6	AP	MP NP	C7970	P7970	1	5	1

	dihydrate 6 micrograms per dose, 120 doses									
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Symbicort Turbuhaler 200/6	AP	MP	C10538	P10538	1	5	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	Inhalation by mouth	BiResp Spiromax	TB	MP NP	C7979 C10121		2	5	2
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	Inhalation by mouth	Bufomix Easyhaler 400/12	OX	MP NP	C7979 C10121		2	5	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	Inhalation by mouth	DuoResp Spiromax	EV	MP NP	C7979 C10121		2	5	1
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	Inhalation by mouth	DuoResp Spiromax	EV	MP NP	C7979 C10121		2	5	2
Budesonide	Powder for oral inhalation in	Inhalation	Rilast	XT	MP NP	C7979 C10121		2	5	1

with formoterol	breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	by mouth	TURBUHALER 400/12							
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	Inhalation by mouth	Symbicort TURBUHALER 400/12	AP	MP NP	C7979 C10121		2	5	1
Budesonide with formoterol	Pressurised inhalation containing budesonide 50 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	Inhalation by mouth	Symbicort Rapihaler 50/3	AP	MP NP	C4397		2	5	1
Budesonide with formoterol	Pressurised inhalation containing budesonide 50 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	Inhalation by mouth	Symbicort Rapihaler 50/3	AP	MP	C10538		2	5	1
Budesonide with formoterol	Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	Inhalation by mouth	Rilast RAPIHALER 100/3	XT	MP NP	C10482	P10482	2	2	1
Budesonide with formoterol	Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	Inhalation by mouth	Rilast RAPIHALER 100/3	XT	MP NP	C4397	P4397	2	5	1
Budesonide	Pressurised inhalation	Inhalation	Rilast RAPIHALER	XT	MP	C10538	P10538	2	5	1

with formoterol	containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	by mouth	100/3							
Budesonide with formoterol	Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	Inhalation by mouth	Symbicort Rapihaler 100/3	AP	MP NP	C10482	P10482	2	2	1
Budesonide with formoterol	Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	Inhalation by mouth	Symbicort Rapihaler 100/3	AP	MP NP	C4397	P4397	2	5	1
Budesonide with formoterol	Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	Inhalation by mouth	Symbicort Rapihaler 100/3	AP	MP	C10538	P10538	2	5	1
Budesonide with formoterol	Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Rilast RAPIHALER 200/6	XT	MP NP	C4404 C10121		2	5	1
Budesonide with formoterol	Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Rilast RAPIHALER 200/6	XT	MP	C10538		2	5	1
Budesonide with formoterol	Pressurised inhalation containing budesonide 200 micrograms with	Inhalation by mouth	Symbicort Rapihaler 200/6	AP	MP NP	C4404 C10121		2	5	1

	formoterol fumarate dihydrate 6 micrograms per dose, 120 doses									
Budesonide with formoterol	Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	Symbicort Rapihaler 200/6	AP	MP	C10538		2	5	1

[27] Schedule 1, Part 1, entry for Cefepime in the form Powder for injection 1 g (as hydrochloride)

omit:

Cefepime	Powder for injection 1 g (as hydrochloride)	Injection	Omegapharm Pty Ltd	OE	MP NP	C5842		10	0	1

[28] Schedule 1, Part 1, entry for Cefepime in the form Powder for injection 2 g (as hydrochloride)

omit:

Cefepime	Powder for injection 2 g (as hydrochloride)	Injection	Omegapharm Pty Ltd	OE	MP NP	C5842		10	0	1

[29] Schedule 1, Part 1, entry for Ceftriaxone in the form Powder for injection 1 g (as sodium)

omit:

Ceftriaxone	Powder for injection 1 g (as sodium)	Injection	Ceftriaxone Alphapharm	AF	MP NP	C5830 C5862 C5868		5	0	5
Ceftriaxone	Powder for injection 1 g (as sodium)	Injection	Ceftriaxone Alphapharm	AF	MP NP	C5830 C5862 C5868		5	0	10

[30] Schedule 1, Part 1, entry for Dapagliflozin

substitute:

Dapagliflozin	Tablet 10 mg (as propanediol monohydrate)	Oral	Forxiga	AP	MP NP	C13230 C14471 C15047 C15311	P13230 P14471 P15047 P15311	28	5	28
Dapagliflozin	Tablet 10 mg (as propanediol	Oral	Forxiga	AP	MP NP	C15051 C15265	P15051 P15265	56	5	56

	monohydrate)										

[31] Schedule 1, Part 1, entry for Dapagliflozin with metformin

substitute:

Dapagliflozin with metformin	Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride	Oral	Xigduo XR 5/1000	AP	MP NP	C15289	P15289	56	5		56
Dapagliflozin with metformin	Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride	Oral	Xigduo XR 5/1000	AP	MP NP	C15267	P15267	112	5		56
Dapagliflozin with metformin	Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride	Oral	Xigduo XR 10/1000	AP	MP NP	C15289	P15289	28	5		28
Dapagliflozin with metformin	Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride	Oral	Xigduo XR 10/1000	AP	MP NP	C15267	P15267	56	5		28
Dapagliflozin with metformin	Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride	Oral	Xigduo XR 10/500	AP	MP NP	C15289	P15289	28	5		28
Dapagliflozin with metformin	Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride	Oral	Xigduo XR 10/500	AP	MP NP	C15267	P15267	56	5		28

[32] Schedule 1, Part 1, entry for Deucravacitinib

omit from the column headed "Circumstances": **C14384** *substitute:* **C15330**

[33] Schedule 1, Part 1, entry for Dicloxacillin in the form Capsule 250 mg (as sodium)

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

Dicloxacillin	Capsule 250 mg (as sodium)	Oral	DICLOXACILLIN VIATRIS 250	MQ	PDP	C5268	24	0	24
Dicloxacillin	Capsule 250 mg (as sodium)	Oral	DICLOXACILLIN VIATRIS 250	MQ	MP NP MW	C5415	24	0	24

[34] Schedule 1, Part 1, entry for Dosulepin in the form Capsule containing dosulepin hydrochloride 25 mg

omit:

Dosulepin	Capsule containing dosulepin hydrochloride 25 mg	Oral	Dosulepin Mylan	AL	MP NP		50	2	50

[35] Schedule 1, Part 1, entry for Dulaglutide

omit from the column headed "Circumstances": **C5469 C5478 C7645** *substitute:* **C15263 C15301**

[36] Schedule 1, Part 1, entry for Empagliflozin

substitute:

Empagliflozin	Tablet 10 mg	Oral	Jardiance	BY	MP NP	C13230 C14471 C15047 C15311	P13230 P14471 P15047 P15311	30	5	30
Empagliflozin	Tablet 10 mg	Oral	Jardiance	BY	MP NP	C15051 C15265	P15051 P15265	60	5	30
Empagliflozin	Tablet 25 mg	Oral	Jardiance	BY	MP NP	C15311	P15311	30	5	30
Empagliflozin	Tablet 25 mg	Oral	Jardiance	BY	MP NP	C15265	P15265	60	5	30

[37] Schedule 1, Part 1, entry for Empagliflozin with linagliptin

substitute:

Empagliflozin with linagliptin	Tablet containing 10 mg empagliflozin with 5 mg	Oral	Glyxambi	BY	MP NP	C15269	P15269	30	5	30

	linagliptin									
Empagliflozin with linagliptin	Tablet containing 10 mg empagliflozin with 5 mg linagliptin	Oral	Glyxambi	BY	MP NP	C15270	P15270	60	5	30
Empagliflozin with linagliptin	Tablet containing 25 mg empagliflozin with 5 mg linagliptin	Oral	Glyxambi	BY	MP NP	C15269	P15269	30	5	30
Empagliflozin with linagliptin	Tablet containing 25 mg empagliflozin with 5 mg linagliptin	Oral	Glyxambi	BY	MP NP	C15270	P15270	60	5	30

[38] Schedule 1, Part 1, entry for Empagliflozin with metformin

substitute:

Empagliflozin with metformin	Tablet containing 5 mg empagliflozin with 1 g metformin hydrochloride	Oral	Jardiamet 5 mg/1000 mg	BY	MP NP	C15289	P15289	60	5	60
Empagliflozin with metformin	Tablet containing 5 mg empagliflozin with 1 g metformin hydrochloride	Oral	Jardiamet 5 mg/1000 mg	BY	MP NP	C15267	P15267	120	5	60
Empagliflozin with metformin	Tablet containing 5 mg empagliflozin with 500 mg metformin hydrochloride	Oral	Jardiamet 5 mg/500 mg	BY	MP NP	C15289	P15289	60	5	60
Empagliflozin with metformin	Tablet containing 5 mg empagliflozin with 500 mg metformin hydrochloride	Oral	Jardiamet 5 mg/500 mg	BY	MP NP	C15267	P15267	120	5	60
Empagliflozin with metformin	Tablet containing 12.5 mg empagliflozin with 1 g metformin hydrochloride	Oral	Jardiamet 12.5 mg/1000 mg	BY	MP NP	C15289	P15289	60	5	60
Empagliflozin with metformin	Tablet containing 12.5 mg empagliflozin with 1 g metformin hydrochloride	Oral	Jardiamet 12.5 mg/1000 mg	BY	MP NP	C15267	P15267	120	5	60
Empagliflozin with metformin	Tablet containing 12.5 mg empagliflozin with 500 mg	Oral	Jardiamet 12.5 mg/500 mg	BY	MP NP	C15289	P15289	60	5	60

	metformin hydrochloride									
Empagliflozin with metformin	Tablet containing 12.5 mg empagliflozin with 500 mg metformin hydrochloride	Oral	Jardiamet 12.5 mg/500 mg	BY	MP NP	C15267	P15267	120	5	60

[39] Schedule 1, Part 1, entry for Enalapril in the form Tablet containing enalapril maleate 5 mg

omit:

Enalapril	Tablet containing enalapril maleate 5 mg	Oral	Enalapril generichealth	GQ	MP NP			30	5	30
Enalapril	Tablet containing enalapril maleate 5 mg	Oral	Enalapril generichealth	GQ	MP NP		P14238	60	5	30

[40] Schedule 1, Part 1, entry for Enalapril in the form Tablet containing enalapril maleate 10 mg

omit:

Enalapril	Tablet containing enalapril maleate 10 mg	Oral	Enalapril generichealth	GQ	MP NP			30	5	30
Enalapril	Tablet containing enalapril maleate 10 mg	Oral	Enalapril generichealth	GQ	MP NP		P14238	60	5	30

[41] Schedule 1, Part 1, entry for Estradiol in the form Transdermal patches 585 micrograms, 8

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

Estradiol	Transdermal patches 585 micrograms, 8	Transdermal	Estradiol Transdermal System (Sandoz, USA)	HX	MP NP			1	5	1

[42] Schedule 1, Part 1, entry for Estradiol in the form Transdermal patches 1.17 mg, 8

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

Estradiol	Transdermal patches 1.17 mg, 8	Transdermal	Estradiol Transdermal System (Sandoz, USA)	HX	MP NP			1	5	1

[43] Schedule 1, Part 1, entry for Estradiol in the form Transdermal patches 1.56 mg, 8

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

Estradiol	Transdermal patches 1.56 mg, 8	Transdermal	Estradiol Transdermal System (Sandoz, USA)	HX	MP NP			1	5	1

[44] Schedule 1, Part 1, entry for Furosemide in the form Tablet 20 mg

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

Furosemide	Tablet 20 mg	Oral	UREMIDE 20	AF	MP NP			100	1	50
Furosemide	Tablet 20 mg	Oral	UREMIDE 20	AF	MP NP			100	1	100
Furosemide	Tablet 20 mg	Oral	UREMIDE 20	AF	MP NP		P14238	200	1	50
Furosemide	Tablet 20 mg	Oral	UREMIDE 20	AF	MP NP		P14238	200	1	100

[45] Schedule 1, Part 1, entry for Inclisiran in the form Injection 284 mg in 1.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 0]*

(a) *insert in numerical order in the column headed "Circumstances":* **C15313 C15323**

(b) *insert in numerical order in the column headed "Purposes":* **P15313 P15323**

[46] Schedule 1, Part 1, entry for Inclisiran in the form Injection 284 mg in 1.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 1]*

(a) *omit from the column headed "Circumstances":* **C15122 C15132 C15144 C15153** *substitute:* **C15315 C15331**

(b) *omit from the column headed "Purposes":* **P15122 P15132 P15144 P15153** *substitute:* **P15315 P15331**

[47] Schedule 1, Part 1, after entry for Ivabradine in the form Tablet 7.5 mg (as hydrochloride) *[Brand: Coralan]*

insert:

Ivacaftor	Sachet containing granules 25 mg	Oral	Kalydeco	VR	MP	See Note 3	See Note 3	See Note 3	See Note 3	56	D(100)

[48] Schedule 1, Part 1, omit entry for Ketoconazole

[49] Schedule 1, Part 1, entry for Lamivudine with zidovudine

omit:

Lamivudine with zidovudine	Tablet 150 mg-300 mg	Oral	Lamivudine 150 mg + Zidovudine 300 mg Alphapharm	AF	MP NP	C4454 C4512		120	5	60	D(100)

[50] Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 4 mg (as mesilate) ***[Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C14007**

(b) *omit from the column headed "Purposes":* **P14007**

[51] Schedule 1, Part 1, entry for Lenvatinib in the form Capsule 10 mg (as mesilate)

omit from the column headed "Circumstances": **C14007**

[52] Schedule 1, Part 1, entry for Linagliptin

substitute:

Linagliptin	Tablet 5 mg	Oral	Trajenta	BY	MP NP	C15261	P15261	30	5	30
Linagliptin	Tablet 5 mg	Oral	Trajenta	BY	MP NP	C15287	P15287	60	5	30

[53] Schedule 1, Part 1, entry for Linagliptin with metformin

substitute:

Linagliptin with metformin	Tablet containing 2.5 mg linagliptin with 1000 mg metformin hydrochloride	Oral	Trajentamet	BY	MP NP	C15276	P15276	60	5	60
Linagliptin with metformin	Tablet containing 2.5 mg linagliptin with 1000 mg metformin hydrochloride	Oral	Trajentamet	BY	MP NP	C15288	P15288	120	5	60
Linagliptin with metformin	Tablet containing 2.5 mg linagliptin with 500 mg metformin hydrochloride	Oral	Trajentamet	BY	MP NP	C15276	P15276	60	5	60

Linagliptin with metformin	Tablet containing 2.5 mg linagliptin with 500 mg metformin hydrochloride	Oral	Trajentamet	BY	MP NP	C15288	P15288	120	5	60
Linagliptin with metformin	Tablet containing 2.5 mg linagliptin with 850 mg metformin hydrochloride	Oral	Trajentamet	BY	MP NP	C15276	P15276	60	5	60
Linagliptin with metformin	Tablet containing 2.5 mg linagliptin with 850 mg metformin hydrochloride	Oral	Trajentamet	BY	MP NP	C15288	P15288	120	5	60

[54] Schedule 1, Part 1, after entry for Medroxyprogesterone in the form Injection containing medroxyprogesterone acetate 150 mg in 1 mL *[Brand: Depo-Ralovera]*

insert:

Medroxyprogesterone	Injection containing medroxyprogesterone acetate 150 mg in 1 mL pre-filled syringe	Injection	Depo-Provera	PF	MP NP			1	1	1

[55] Schedule 1, Part 1, entry for Methotrexate in the form Tablet 2.5 mg

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

Methotrexate	Tablet 2.5 mg	Oral	ARX-Methotrexate	XT	MP NP			30	5	30

[56] Schedule 1, Part 1, entry for Methotrexate in the form Tablet 10 mg

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

Methotrexate	Tablet 10 mg	Oral	ARX-Methotrexate	XT	MP NP			15	3	15
Methotrexate	Tablet 10 mg	Oral	ARX-Methotrexate	XT	MP NP		P5648	50	2	50

[57] Schedule 1, Part 1, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg

omit:

Mycophenolic acid	Tablet containing mycophenolate mofetil	Oral	Noumed Mycophenolate	VO	MP			150	5	50

	500 mg										
Mycophenolic acid	Tablet containing mycophenolate mofetil 500 mg	Oral	Noumed Mycophenolate	VO	MP		P14238	300	5	50	

[58] Schedule 1, Part 1, entry for Naltrexone

omit:

Naltrexone	Tablet containing naltrexone hydrochloride 50 mg	Oral	ARX-NALTREXONE	XT	MP NP	C13967		30	1	30	

[59] Schedule 1, Part 1, entry for Nebivolol in the form Tablet 1.25 mg (as hydrochloride)

omit:

Nebivolol	Tablet 1.25 mg (as hydrochloride)	Oral	Nebivolol Viatris	AL	MP NP	C5324	P5324	56	5	28	
Nebivolol	Tablet 1.25 mg (as hydrochloride)	Oral	Nebivolol Viatris	AL	MP NP	C14251	P14251	112	5	28	

[60] Schedule 1, Part 1, entry for Nebivolol in the form Tablet 10 mg (as hydrochloride)

omit:

Nebivolol	Tablet 10 mg (as hydrochloride)	Oral	Nebivolol Viatris	AL	MP NP	C5324	P5324	28	5	28	
Nebivolol	Tablet 10 mg (as hydrochloride)	Oral	Nebivolol Viatris	AL	MP NP	C14251	P14251	56	5	28	

[61] Schedule 1, Part 1, entry for Nivolumab

substitute:

Nivolumab	Injection concentrate for I.V. infusion 40 mg in 4 mL	Injection	Opdivo	BQ	MP	C14830	P14830	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 40 mg in 4 mL	Injection	Opdivo	BQ	MP	C14001	P14001	See Note 3	See Note 3	1	D(100)

Nivolumab	Injection concentrate for I.V. infusion 40 mg in 4 mL	Injection	Opdivo	BQ	MP	C11985	P11985	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 40 mg in 4 mL	Injection	Opdivo	BQ	MP	C11468 C13433	P11468 P13433	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 40 mg in 4 mL	Injection	Opdivo	BQ	MP	C10119 C10120 C13900	P10119 P10120 P13900	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 40 mg in 4 mL	Injection	Opdivo	BQ	MP	C9216 C9312 C13445 C14816	P9216 P9312 P13445 P14816	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 40 mg in 4 mL	Injection	Opdivo	BQ	MP	C9252 C9298 C9299 C9321 C11477 C13839	P9252 P9298 P9299 P9321 P11477 P13839	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 40 mg in 4 mL	Injection	Opdivo	BQ	MP	C14676	P14676	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 100 mg in 10 mL	Injection	Opdivo	BQ	MP	C14830	P14830	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 100 mg in 10 mL	Injection	Opdivo	BQ	MP	C14001	P14001	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 100 mg in 10 mL	Injection	Opdivo	BQ	MP	C11985	P11985	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 100 mg in 10 mL	Injection	Opdivo	BQ	MP	C11468 C13433	P11468 P13433	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 100 mg in 10 mL	Injection	Opdivo	BQ	MP	C10119 C10120 C13900	P10119 P10120 P13900	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 100 mg in 10 mL	Injection	Opdivo	BQ	MP	C9216 C9312 C13445 C14816	P9216 P9312 P13445 P14816	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 100 mg in 10 mL	Injection	Opdivo	BQ	MP	C9252 C9298 C9299 C9321 C11477 C13839	P9252 P9298 P9299 P9321 P11477 P13839	See Note 3	See Note 3	1	D(100)
Nivolumab	Injection concentrate for I.V. infusion 100 mg in 10 mL	Injection	Opdivo	BQ	MP	C14676	P14676	See Note 3	See Note 3	1	D(100)

[62] Schedule 1, Part 1, entry for Olanzapine in the form Tablet 10 mg

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

Olanzapine	Tablet 10 mg	Oral	APO-OLANZAPINE	TX	MP NP	C5856 C5869		28	5	28

[63] Schedule 1, Part 1, entry for Onasemnogene abeparvovec

substitute:

Onasemnogene abeparvovec	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 1 vial solution for I.V. infusion	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

	20 trillion vector genomes per mL, 5.5 mL and 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL										
Onasemnogene abeparvovec	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 8 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 1 vial solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 3 vials solution for I.V. infusion 20 trillion vector genomes	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

	per mL, 8.3 mL										
Onasemnogene abeparvovec	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 5.5 mL and 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 2 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 3 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

Onasemnogene abeparvovec	Pack containing 4 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 5 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 6 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 7 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 8 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Onasemnogene abeparvovec	Pack containing 9 vials solution for I.V. infusion 20 trillion vector genomes per mL, 8.3 mL	Injection	Zolgensma	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[64] Schedule 1, Part 1, entry for Ondansetron

substitute:

Ondansetron	Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL	Oral	Zofran syrup 50 mL	AS	MP NP	C5721	P5721	1	0	V5721	1	
Ondansetron	Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL	Oral	Zofran syrup 50 mL	AS	MP	C5778	P5778	1	0	V5778	1	C(100)
Ondansetron	Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL	Oral	Zofran syrup 50 mL	AS	MP NP	C15193	P15193	1	1		1	
Ondansetron	Tablet 4 mg (as	Oral	APO-Ondansetron	TX	MP NP	C4118	P4118	4	0	V4118	4	

	hydrochloride dihydrate)											
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	APX-Ondansetron	TY	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	APX-Ondansetron	TY	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	APX-Ondansetron	TY	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Ondansetron Mylan Tablets	AF	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Ondansetron Mylan Tablets	AF	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Ondansetron Mylan Tablets	AF	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Ondansetron SZ	HX	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Ondansetron SZ	HX	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Ondansetron SZ	HX	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Ondansetron Tablets Viatris	AL	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Ondansetron Tablets Viatris	AL	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Ondansetron Tablets Viatris	AL	MP NP	C15193	P15193	10	1		10	

Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Ondansetron-DRLA	RZ	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Ondansetron-DRLA	RZ	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Ondansetron-DRLA	RZ	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Zofran	AS	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Zofran	AS	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Zofran	AS	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Zotren 4	RF	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Zotren 4	RF	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 4 mg (as hydrochloride dihydrate)	Oral	Zotren 4	RF	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	APX-Ondansetron ODT	TY	MP NP	C5618	P5618	4	0	V5618	4	
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	APX-Ondansetron ODT	TY	MP	C5743	P5743	4	0	V5743	4	C(100)
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	APX-Ondansetron ODT	TY	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron Mylan ODT	AF	MP NP	C5618	P5618	4	0	V5618	4	
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron Mylan ODT	AF	MP	C5743	P5743	4	0	V5743	4	C(100)
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron Mylan ODT	AF	MP NP	C15193	P15193	10	1		10	

Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron ODT-DRLA	RZ	MP NP	C5618	P5618	4	0	V5618	4	
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron ODT-DRLA	RZ	MP	C5743	P5743	4	0	V5743	4	C(100)
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron ODT-DRLA	RZ	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron ODT Lupin	HQ	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron SZ ODT	HX	MP NP	C5618	P5618	4	0	V5618	4	
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron SZ ODT	HX	MP	C5743	P5743	4	0	V5743	4	C(100)
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Ondansetron SZ ODT	HX	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Zotren ODT	RF	MP NP	C5618	P5618	4	0	V5618	4	
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Zotren ODT	RF	MP	C5743	P5743	4	0	V5743	4	C(100)
Ondansetron	Tablet (orally disintegrating) 4 mg	Oral	Zotren ODT	RF	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron	TX	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	APX-Ondansetron	TY	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	APX-Ondansetron	TY	MP	C5778	P5778	4	0	V5778	4	C(100)

Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	APX-Ondansetron	TY	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Ondansetron Mylan Tablets	AF	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Ondansetron Mylan Tablets	AF	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Ondansetron Mylan Tablets	AF	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Ondansetron SZ	HX	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Ondansetron SZ	HX	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Ondansetron SZ	HX	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Ondansetron Tablets Viatris	AL	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Ondansetron Tablets Viatris	AL	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Ondansetron Tablets Viatris	AL	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Ondansetron-DRLA	RZ	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Ondansetron-DRLA	RZ	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Ondansetron-DRLA	RZ	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Zofran	AS	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Zofran	AS	MP	C5778	P5778	4	0	V5778	4	C(100)

Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Zofran	AS	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Zotren 8	RF	MP NP	C4118	P4118	4	0	V4118	4	
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Zotren 8	RF	MP	C5778	P5778	4	0	V5778	4	C(100)
Ondansetron	Tablet 8 mg (as hydrochloride dihydrate)	Oral	Zotren 8	RF	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	APX-Ondansetron ODT	TY	MP NP	C5618	P5618	4	0	V5618	4	
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	APX-Ondansetron ODT	TY	MP	C5743	P5743	4	0	V5743	4	C(100)
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	APX-Ondansetron ODT	TY	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron Mylan ODT	AF	MP NP	C5618	P5618	4	0	V5618	4	
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron Mylan ODT	AF	MP	C5743	P5743	4	0	V5743	4	C(100)
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron Mylan ODT	AF	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron ODT Viatris	AL	MP NP	C5618	P5618	4	0	V5618	4	
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron ODT Viatris	AL	MP	C5743	P5743	4	0	V5743	4	C(100)
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron ODT Viatris	AL	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron ODT-DRLA	RZ	MP NP	C5618	P5618	4	0	V5618	4	
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron ODT-DRLA	RZ	MP	C5743	P5743	4	0	V5743	4	C(100)

Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron ODT-DRLA	RZ	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron ODT Lupin	HQ	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron SZ ODT	HX	MP NP	C5618	P5618	4	0	V5618	4	
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron SZ ODT	HX	MP	C5743	P5743	4	0	V5743	4	C(100)
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Ondansetron SZ ODT	HX	MP NP	C15193	P15193	10	1		10	
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Zotren ODT	RF	MP NP	C5618	P5618	4	0	V5618	4	
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Zotren ODT	RF	MP	C5743	P5743	4	0	V5743	4	C(100)
Ondansetron	Tablet (orally disintegrating) 8 mg	Oral	Zotren ODT	RF	MP NP	C15193	P15193	10	1		10	
Ondansetron	Wafer 4 mg	Oral	Zofran Zydis	AS	MP NP	C15193		10	1		10	
Ondansetron	Wafer 8 mg	Oral	Zofran Zydis	AS	MP NP	C15193		10	1		10	

[65] Schedule 1, Part 1, entry for Osimertinib in the form Tablet 40 mg

omit from the column headed "Circumstances": **C11181 C11183** *substitute:* **C15257 C15283 C15310**

[66] Schedule 1, Part 1, entry for Osimertinib in the form Tablet 80 mg

omit from the column headed "Circumstances": **C11178 C11181 C11183 C11185** *substitute:* **C15257 C15281 C15283 C15299 C15329**

[67] Schedule 1, Part 1, entry for Ozanimod in the form Capsule 920 micrograms *[Maximum Quantity: 28; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C13993**

(b) *omit from the column headed "Purposes":* **P13993**

[68] Schedule 1, Part 1, entry for Pembrolizumab

substitute:

Pembrolizumab	Solution concentrate for I.V. infusion 100 mg in 4 mL	Injection	Keytruda	MK	MP	C14818	P14818	See Note 3	See Note 3	1	D(100)
Pembrolizumab	Solution concentrate for I.V. infusion 100 mg in 4 mL	Injection	Keytruda	MK	MP	C13431 C13432	P13431 P13432	See Note 3	See Note 3	1	D(100)
Pembrolizumab	Solution concentrate for I.V. infusion 100 mg in 4 mL	Injection	Keytruda	MK	MP	C10705 C14770 C14786	P10705 P14770 P14786	See Note 3	See Note 3	1	D(100)
Pembrolizumab	Solution concentrate for I.V. infusion 100 mg in 4 mL	Injection	Keytruda	MK	MP	C14817	P14817	See Note 3	See Note 3	1	D(100)
Pembrolizumab	Solution concentrate for I.V. infusion 100 mg in 4 mL	Injection	Keytruda	MK	MP	C10676 C10688 C10701 C13436 C13437	P10676 P10688 P10701 P13436 P13437	See Note 3	See Note 3	1	D(100)
Pembrolizumab	Solution concentrate for I.V. infusion 100 mg in 4 mL	Injection	Keytruda	MK	MP	C13726 C13727 C13728 C13730 C13731 C13732 C13735 C13736 C13739 C13741 C13948 C13949 C14027 C14028 C14044 C14324 C14403 C14404 C14405	P13726 P13727 P13728 P13730 P13731 P13732 P13735 P13736 P13739 P13741 P13948 P13949 P14027 P14028 P14044 P14324 P14403 P14404 P14405	See Note 3	See Note 3	1	D(100)
Pembrolizumab	Solution concentrate for I.V. infusion 100 mg in 4 mL	Injection	Keytruda	MK	MP	C14727	P14727	See Note 3	See Note 3	1	D(100)

[69] Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 2.5 mg

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

Perindopril	Tablet containing perindopril arginine 2.5 mg	Oral	Perindopril Arginine Sandoz	SZ	MP NP		30	5	30
Perindopril	Tablet containing perindopril arginine 2.5 mg	Oral	Perindopril Arginine Sandoz	SZ	MP NP	P14238	60	5	30

[70] Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 5 mg

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

Perindopril	Tablet containing perindopril arginine 5 mg	Oral	Perindopril Arginine Sandoz	SZ	MP NP			30	5	30
Perindopril	Tablet containing perindopril arginine 5 mg	Oral	Perindopril Arginine Sandoz	SZ	MP NP		P14238	60	5	30

[71] Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 10 mg

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

Perindopril	Tablet containing perindopril arginine 10 mg	Oral	Perindopril Arginine Sandoz	SZ	MP NP			30	5	30
Perindopril	Tablet containing perindopril arginine 10 mg	Oral	Perindopril Arginine Sandoz	SZ	MP NP		P14238	60	5	30

[72] Schedule 1, Part 1, entry for Pioglitazone

substitute:

Pioglitazone	Tablet 15 mg (as hydrochloride)	Oral	Acpio 15	RF	MP NP	C15321	P15321	28	5	28
Pioglitazone	Tablet 15 mg (as hydrochloride)	Oral	Acpio 15	RF	MP NP	C15290	P15290	56	5	28
Pioglitazone	Tablet 15 mg (as hydrochloride)	Oral	Actaze	RW	MP NP	C15321	P15321	28	5	28
Pioglitazone	Tablet 15 mg (as hydrochloride)	Oral	Actaze	RW	MP NP	C15290	P15290	56	5	28
Pioglitazone	Tablet 15 mg (as hydrochloride)	Oral	Actos	EW	MP NP	C15321	P15321	28	5	28
Pioglitazone	Tablet 15 mg (as hydrochloride)	Oral	Actos	EW	MP NP	C15290	P15290	56	5	28
Pioglitazone	Tablet 15 mg (as hydrochloride)	Oral	APOTEX-Pioglitazone	TX	MP NP	C15321	P15321	28	5	28
Pioglitazone	Tablet 15 mg (as hydrochloride)	Oral	APOTEX-Pioglitazone	TX	MP NP	C15290	P15290	56	5	28

Pioglitazone	Tablet 15 mg (as hydrochloride)	Oral	Vexazone	AF	MP NP	C15321	P15321	28	5	28
Pioglitazone	Tablet 15 mg (as hydrochloride)	Oral	Vexazone	AF	MP NP	C15290	P15290	56	5	28
Pioglitazone	Tablet 30 mg (as hydrochloride)	Oral	Acpio 30	RF	MP NP	C15321	P15321	28	5	28
Pioglitazone	Tablet 30 mg (as hydrochloride)	Oral	Acpio 30	RF	MP NP	C15290	P15290	56	5	28
Pioglitazone	Tablet 30 mg (as hydrochloride)	Oral	Actaze	RW	MP NP	C15321	P15321	28	5	28
Pioglitazone	Tablet 30 mg (as hydrochloride)	Oral	Actaze	RW	MP NP	C15290	P15290	56	5	28
Pioglitazone	Tablet 30 mg (as hydrochloride)	Oral	Actos	EW	MP NP	C15321	P15321	28	5	28
Pioglitazone	Tablet 30 mg (as hydrochloride)	Oral	Actos	EW	MP NP	C15290	P15290	56	5	28
Pioglitazone	Tablet 30 mg (as hydrochloride)	Oral	APOTEX-Pioglitazone	TX	MP NP	C15321	P15321	28	5	28
Pioglitazone	Tablet 30 mg (as hydrochloride)	Oral	APOTEX-Pioglitazone	TX	MP NP	C15290	P15290	56	5	28
Pioglitazone	Tablet 30 mg (as hydrochloride)	Oral	Vexazone	AF	MP NP	C15321	P15321	28	5	28
Pioglitazone	Tablet 30 mg (as hydrochloride)	Oral	Vexazone	AF	MP NP	C15290	P15290	56	5	28
Pioglitazone	Tablet 45 mg (as hydrochloride)	Oral	Acpio 45	RF	MP NP	C15321	P15321	28	5	28
Pioglitazone	Tablet 45 mg (as hydrochloride)	Oral	Acpio 45	RF	MP NP	C15290	P15290	56	5	28
Pioglitazone	Tablet 45 mg (as hydrochloride)	Oral	Actaze	RW	MP NP	C15321	P15321	28	5	28

Pioglitazone	Tablet 45 mg (as hydrochloride)	Oral	Actaze	RW	MP NP	C15290	P15290	56	5	28	
Pioglitazone	Tablet 45 mg (as hydrochloride)	Oral	Actos	EW	MP NP	C15321	P15321	28	5	28	
Pioglitazone	Tablet 45 mg (as hydrochloride)	Oral	Actos	EW	MP NP	C15290	P15290	56	5	28	
Pioglitazone	Tablet 45 mg (as hydrochloride)	Oral	APOTEX-Pioglitazone	TX	MP NP	C15321	P15321	28	5	28	
Pioglitazone	Tablet 45 mg (as hydrochloride)	Oral	APOTEX-Pioglitazone	TX	MP NP	C15290	P15290	56	5	28	
Pioglitazone	Tablet 45 mg (as hydrochloride)	Oral	Vexazone	AF	MP NP	C15321	P15321	28	5	28	
Pioglitazone	Tablet 45 mg (as hydrochloride)	Oral	Vexazone	AF	MP NP	C15290	P15290	56	5	28	

[73] Schedule 1, Part 1, entry for Plerixafor

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

Plerixafor	Injection 24 mg in 1.2 mL	Injection	PLERIXAFOR EUGIA	YG	MP	C4549 C9329	1	1	1	D(100)

[74] Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 50 mg (as fumarate)

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

Quetiapine	Tablet (modified release) 50 mg (as fumarate)	Oral	Quetiapine Sandoz XR	SZ	MP NP	C4246 C5611 C5639	60	5	60	

[75] Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 150 mg (as fumarate)

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

Quetiapine	Tablet (modified release) 150 mg (as fumarate)	Oral	Quetiapine Sandoz XR	SZ	MP NP	C4246 C5611 C5639	60	5	60	

[76] Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 200 mg (as fumarate)

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

Quetiapine	Tablet (modified release) 200 mg (as fumarate)	Oral	Quetiapine Sandoz XR	SZ	MP NP	C4246 C5611 C5639		60	5	60

[77] Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 300 mg (as fumarate)

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

Quetiapine	Tablet (modified release) 300 mg (as fumarate)	Oral	Quetiapine Sandoz XR	SZ	MP NP	C4246 C5611 C5639		60	5	60

[78] Schedule 1, Part 1, entry for Quetiapine in the form Tablet (modified release) 400 mg (as fumarate)

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

Quetiapine	Tablet (modified release) 400 mg (as fumarate)	Oral	Quetiapine Sandoz XR	SZ	MP NP	C4246 C5611 C5639		60	5	60

[79] Schedule 1, Part 1, entry for Ramipril in the form Tablet 2.5 mg

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

Ramipril	Tablet 2.5 mg	Oral	Ramipril Viatris	AL	MP NP			30	5	30
Ramipril	Tablet 2.5 mg	Oral	Ramipril Viatris	AL	MP NP		P14238	60	5	30

[80] Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 5 mg (as calcium)

omit:

Rosuvastatin	Tablet 5 mg (as calcium)	Oral	Noumed Rosuvastatin	VO	MP NP			30	5	30
Rosuvastatin	Tablet 5 mg (as calcium)	Oral	Noumed Rosuvastatin	VO	MP NP		P14238	60	5	30

[81] Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 10 mg (as calcium)

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

Rosuvastatin	Tablet 10 mg (as calcium)	Oral	APO-ROSUVASTATIN	TX	MP NP			30	5	30	
Rosuvastatin	Tablet 10 mg (as calcium)	Oral	APO-ROSUVASTATIN	TX	MP NP		P14238	60	5	30	

(b) *omit:*

Rosuvastatin	Tablet 10 mg (as calcium)	Oral	Noumed Rosuvastatin	VO	MP NP			30	5	30	
Rosuvastatin	Tablet 10 mg (as calcium)	Oral	Noumed Rosuvastatin	VO	MP NP		P14238	60	5	30	

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

omit:

Rosuvastatin	Tablet 20 mg (as calcium)	Oral	Noumed Rosuvastatin	VO	MP NP			30	5	30	
Rosuvastatin	Tablet 20 mg (as calcium)	Oral	Noumed Rosuvastatin	VO	MP NP		P14238	60	5	30	

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

omit:

Rosuvastatin	Tablet 40 mg (as calcium)	Oral	Noumed Rosuvastatin	VO	MP NP			30	5	30	
Rosuvastatin	Tablet 40 mg (as calcium)	Oral	Noumed Rosuvastatin	VO	MP NP		P14238	60	5	30	

[84] Schedule 1, Part 1, entry for Ruxolitinib

substitute:

Ruxolitinib	Tablet 5 mg	Oral	Jakavi	NV	MP	C13907 C13911	P13907 P13911	56	0	56	C(100)
Ruxolitinib	Tablet 5 mg	Oral	Jakavi	NV	MP	C13867 C13906	P13867 P13906	56	5	56	
Ruxolitinib	Tablet 5 mg	Oral	Jakavi	NV	MP	C13876 C13892	P13876 P13892	56	5	56	C(100)

Ruxolitinib	Tablet 5 mg	Oral	Jakavi	NV	MP	C13127 C13173	P13127 P13173	112	0	56	
Ruxolitinib	Tablet 5 mg	Oral	Jakavi	NV	MP	C13128 C13130	P13128 P13130	112	5	56	
Ruxolitinib	Tablet 10 mg	Oral	Jakavi	NV	MP	C13127 C13173	P13127 P13173	56	0	56	
Ruxolitinib	Tablet 10 mg	Oral	Jakavi	NV	MP	C13907 C13911	P13907 P13911	56	0	56	C(100)
Ruxolitinib	Tablet 10 mg	Oral	Jakavi	NV	MP	C13128 C13130 C13867 C13906	P13128 P13130 P13867 P13906	56	5	56	
Ruxolitinib	Tablet 10 mg	Oral	Jakavi	NV	MP	C13876 C13892	P13876 P13892	56	5	56	C(100)
Ruxolitinib	Tablet 15 mg	Oral	Jakavi	NV	MP	C13127 C13173	P13127 P13173	56	0	56	
Ruxolitinib	Tablet 15 mg	Oral	Jakavi	NV	MP	C13128 C13130	P13128 P13130	56	5	56	
Ruxolitinib	Tablet 20 mg	Oral	Jakavi	NV	MP	C13127 C13173	P13127 P13173	56	0	56	
Ruxolitinib	Tablet 20 mg	Oral	Jakavi	NV	MP	C13128 C13130	P13128 P13130	56	5	56	

[85] Schedule 1, Part 1, entry for Saxagliptin

substitute:

Saxagliptin	Tablet 2.5 mg (as hydrochloride)	Oral	Onglyza	AP	MP NP	C15261	P15261	28	5	28	
Saxagliptin	Tablet 2.5 mg (as hydrochloride)	Oral	Onglyza	AP	MP NP	C15287	P15287	56	5	28	
Saxagliptin	Tablet 5 mg (as hydrochloride)	Oral	Onglyza	AP	MP NP	C15261	P15261	28	5	28	
Saxagliptin	Tablet 5 mg (as hydrochloride)	Oral	Onglyza	AP	MP NP	C15287	P15287	56	5	28	

[86] Schedule 1, Part 1, entry for Saxagliptin with dapagliflozin

substitute:

Saxagliptin with dapagliflozin	Tablet containing saxagliptin 5 mg with dapaglifozin 10 mg	Oral	Qtern 5/10	AP	MP	C15269	P15269	28	5	28	

Saxagliptin with dapagliflozin	Tablet containing saxagliptin 5 mg with dapaglifozin 10 mg	Oral	Qtern 5/10	AP	MP NP	C15270	P15270	56	5	28

[87] Schedule 1, Part 1, entry for Saxagliptin with metformin

substitute:

Saxagliptin with metformin	Tablet (modified release) containing 2.5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride	Oral	Kombiglyze XR 2.5/1000	AP	MP NP	C15276	P15276	56	5	56
Saxagliptin with metformin	Tablet (modified release) containing 2.5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride	Oral	Kombiglyze XR 2.5/1000	AP	MP NP	C15288	P15288	112	5	56
Saxagliptin with metformin	Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride	Oral	Kombiglyze XR 5/1000	AP	MP NP	C15276	P15276	28	5	28
Saxagliptin with metformin	Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride	Oral	Kombiglyze XR 5/1000	AP	MP NP	C15288	P15288	56	5	28
Saxagliptin with metformin	Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 500 mg metformin hydrochloride	Oral	Kombiglyze XR 5/500	AP	MP NP	C15276	P15276	28	5	28
Saxagliptin with metformin	Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 500 mg metformin hydrochloride	Oral	Kombiglyze XR 5/500	AP	MP NP	C15288	P15288	56	5	28

[88] Schedule 1, Part 1, entry for Secukinumab

substitute:

Secukinumab	Injection 150 mg in 1 mL pre-filled pen	Injection	Cosentyx	NV	MP	C11390 C12392	P11390 P12392	1	0	1
Secukinumab	Injection 150 mg in 1 mL pre-filled pen	Injection	Cosentyx	NV	MP	C9064 C9429	P9064 P9429	1	2	1
Secukinumab	Injection 150 mg in 1 mL pre-filled pen	Injection	Cosentyx	NV	MP	C9063 C9105 C9431 C10431 C14692	P9063 P9105 P9431 P10431 P14692	1	5	1
Secukinumab	Injection 150 mg in 1 mL pre-filled pen	Injection	Cosentyx	NV	MP	C8831 C9064	P8831 P9064	2	2	2
Secukinumab	Injection 150 mg in 1 mL pre-filled pen	Injection	Cosentyx	NV	MP	C15279 C15295 C15316 C15328	P15279 P15295 P15316 P15328	2	3	2
Secukinumab	Injection 150 mg in 1 mL pre-filled pen	Injection	Cosentyx	NV	MP	C6696 C8830 C8892 C9063 C9105 C15317 C15325	P6696 P8830 P8892 P9063 P9105 P15317 P15325	2	5	2
Secukinumab	Injection 150 mg in 1 mL pre-filled pen	Injection	Cosentyx	NV	MP	C9069 C9078 C9155 C14655 C14662 C14670	P9069 P9078 P9155 P14655 P14662 P14670	4	0	1
Secukinumab	Injection 150 mg in 1 mL pre-filled pen	Injection	Cosentyx	NV	MP	C15127 C15137 C15158	P15127 P15137 P15158	5	0	1
Secukinumab	Injection 150 mg in 1 mL pre-filled pen	Injection	Cosentyx	NV	MP	C9069 C9078 C9155 C11089 C11096 C11138 C11154 C14430 C14462 C15280 C15296 C15307	P9069 P9078 P9155 P11089 P11096 P11138 P11154 P14430 P14462 P15280 P15296 P15307	8	0	2

[89] Schedule 1, Part 1, entry for Semaglutide in each of the forms: Solution for injection 2 mg in 1.5 mL pre-filled pen; and Solution for injection 4 mg in 3 mL pre-filled pen

omit from the column headed "Circumstances": **C5469 C5478 C5500** *substitute:* **C15263 C15301**

[90] Schedule 1, Part 1, entry for Sitagliptin

substitute:

Sitagliptin	Tablet 25 mg	Oral	Januvia	XW	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 25 mg	Oral	Januvia	XW	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 25 mg	Oral	Sitagliptin Lupin	GQ	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 25 mg	Oral	Sitagliptin Lupin	GQ	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 25 mg	Oral	Sitagliptin Sandoz Pharma	SZ	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 25 mg	Oral	Sitagliptin Sandoz Pharma	SZ	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 25 mg	Oral	Sitagliptin SUN	RA	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 25 mg	Oral	Sitagliptin SUN	RA	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 25 mg	Oral	Sitaglo	CR	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 25 mg	Oral	Sitaglo	CR	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 25 mg	Oral	Xelevia	XT	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 25 mg	Oral	Xelevia	XT	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 50 mg	Oral	Januvia	XW	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 50 mg	Oral	Januvia	XW	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 50 mg	Oral	Sitagliptin Lupin	GQ	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 50 mg	Oral	Sitagliptin Lupin	GQ	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 50 mg	Oral	Sitagliptin Sandoz Pharma	SZ	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 50 mg	Oral	Sitagliptin Sandoz Pharma	SZ	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 50 mg	Oral	Sitagliptin SUN	RA	MP NP	C15261	P15261	28	5	28

Sitagliptin	Tablet 50 mg	Oral	Sitagliptin SUN	RA	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 50 mg	Oral	Sitaglo	CR	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 50 mg	Oral	Sitaglo	CR	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 50 mg	Oral	Xelevia	XT	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 50 mg	Oral	Xelevia	XT	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 100 mg	Oral	Januvia	XW	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 100 mg	Oral	Januvia	XW	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 100 mg	Oral	Sitagliptin Lupin	GQ	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 100 mg	Oral	Sitagliptin Lupin	GQ	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 100 mg	Oral	Sitagliptin Sandoz Pharma	SZ	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 100 mg	Oral	Sitagliptin Sandoz Pharma	SZ	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 100 mg	Oral	Sitagliptin SUN	RA	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 100 mg	Oral	Sitagliptin SUN	RA	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 100 mg	Oral	Sitaglo	CR	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 100 mg	Oral	Sitaglo	CR	MP NP	C15287	P15287	56	5	28
Sitagliptin	Tablet 100 mg	Oral	Xelevia	XT	MP NP	C15261	P15261	28	5	28
Sitagliptin	Tablet 100 mg	Oral	Xelevia	XT	MP NP	C15287	P15287	56	5	28

[91] Schedule 1, Part 1, entry for Sitagliptin with metformin

substitute:

Sitagliptin with metformin	Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Janumet XR	XW	MP NP	C15276	P15276	56	5	56

Sitagliptin with metformin	Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Janumet XR	XW	MP NP	C15288	P15288	112	5	56
Sitagliptin with metformin	Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Sitagliptin/Metformin Sandoz XR	SZ	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Sitagliptin/Metformin Sandoz XR	SZ	MP NP	C15288	P15288	112	5	56
Sitagliptin with metformin	Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Janumet XR	XW	MP NP	C15276	P15276	28	5	28
Sitagliptin with metformin	Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Janumet XR	XW	MP NP	C15288	P15288	56	5	28
Sitagliptin with metformin	Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Sitagliptin/Metformin Sandoz XR	SZ	MP NP	C15276	P15276	28	5	28
Sitagliptin with metformin	Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Sitagliptin/Metformin Sandoz XR	SZ	MP NP	C15288	P15288	56	5	28
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Janumet	XW	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Janumet	XW	MP NP	C15288	P15288	112	5	56
Sitagliptin with	Tablet containing 50 mg	Oral	SITAGLIPTIN/MET	RA	MP NP	C15276	P15276	56	5	56

metformin	sitagliptin with 1000 mg metformin hydrochloride		FORMIN 50/1000 SUN							
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	SITAGLIPTIN/METFORMIN 50/1000 SUN	RA	MP NP	C15288	P15288	112	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Sitagliptin/Metformin Sandoz	SZ	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Sitagliptin/Metformin Sandoz	SZ	MP NP	C15288	P15288	112	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Velmetia	XT	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	Velmetia	XT	MP NP	C15288	P15288	112	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride	Oral	Janumet	XW	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride	Oral	Janumet	XW	MP NP	C15288	P15288	112	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride	Oral	SITAGLIPTIN/METFORMIN 50/500 SUN	RA	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride	Oral	SITAGLIPTIN/METFORMIN 50/500 SUN	RA	MP NP	C15288	P15288	112	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride	Oral	Sitagliptin/Metformin Sandoz	SZ	MP NP	C15276	P15276	56	5	56
Sitagliptin with	Tablet containing 50 mg sitagliptin with 500 mg	Oral	Sitagliptin/Metformi	SZ	MP NP	C15288	P15288	112	5	56

metformin	metformin hydrochloride		n Sandoz							
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride	Oral	Velmetia	XT	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride	Oral	Velmetia	XT	MP NP	C15288	P15288	112	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride	Oral	Janumet	XW	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride	Oral	Janumet	XW	MP NP	C15288	P15288	112	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride	Oral	SITAGLIPTIN/METFORMIN 50/850 SUN	RA	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride	Oral	SITAGLIPTIN/METFORMIN 50/850 SUN	RA	MP NP	C15288	P15288	112	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride	Oral	Sitagliptin/Metformin Sandoz	SZ	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride	Oral	Sitagliptin/Metformin Sandoz	SZ	MP NP	C15288	P15288	112	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride	Oral	Velmetia	XT	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride	Oral	Velmetia	XT	MP NP	C15288	P15288	112	5	56

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

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

Sumatriptan	Tablet 50 mg (as succinate)	Oral	IMIGRAN MIGRAINE	AS	MP NP	C5259		4	5	2	

[93] Schedule 1, Part 1, entry for Tafamidis

(a) *omit from the column headed "Circumstances":* **C15088**

(b) *insert in numerical order in the column headed "Circumstances":* **C15303**

[94] Schedule 1, Part 1, entry for Tenofovir with emtricitabine

substitute:

Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	Oral	CIPLA TENOFOVIR + EMTRICITABINE 300/200	LR	MP NP	C11143	P11143	30	2	30	
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	Oral	CIPLA TENOFOVIR + EMTRICITABINE 300/200	LR	MP NP	C6985 C6986	P6985 P6986	60	5	30	C(100)
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	Oral	Tenofovir/Emtricitabine 300/200 APOTEX	TX	MP NP	C11143	P11143	30	2	30	
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	Oral	Tenofovir/Emtricitabine 300/200 APOTEX	TX	MP NP	C6985 C6986	P6985 P6986	60	5	30	C(100)
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	Oral	TENOFOVIR/EMTRICITABINE 300/200 ARX	XT	MP NP	C11143	P11143	30	2	30	
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg	Oral	TENOFOVIR/EMTRICITABINE 300/200 ARX	XT	MP NP	C6985 C6986	P6985 P6986	60	5	30	C(100)
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil maleate 300 mg	Oral	Tenofovir Disoproxil Emtricitabine Viatris	AL	MP NP	C11143	P11143	30	2	30	

	with emtricitabine 200 mg		300/200									
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg	Oral	Tenofovir Disoproxil Emtricitabine Viatris 300/200	AL	MP NP	C6985 C6986	P6985 P6986	60	5	30	C(100)
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg	Oral	Tenofovir EMT GH	GQ	MP NP	C11143	P11143	30	2	30	
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg	Oral	Tenofovir EMT GH	GQ	MP NP	C6985 C6986	P6985 P6986	60	5	30	C(100)
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg	Oral	Tenofovir/Emtricitabine Sandoz 301/200	SZ	MP NP	C11143	P11143	30	2	30	
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg	Oral	Tenofovir/Emtricitabine Sandoz 301/200	SZ	MP NP	C6985 C6986	P6985 P6986	60	5	30	C(100)

[95] Schedule 1, Part 1, entry for Teriparatide in the form Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled cartridge *[Maximum Quantity: 2; Number of Repeats: 5]*

omit from the column headed "Number of Repeats": **5** *substitute:* **2**

[96] Schedule 1, Part 1, entry for Testosterone in the form I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL

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

Testosterone	I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL	Injection	Testosterone ADVZ 1000	BZ	MP	C6324 C6910 C6919 C6933 C6934	1	1	1

[97] Schedule 1, Part 1, entry for Tobramycin in the form Solution for inhalation 300 mg in 5 mL *[Brand: Tobramycin WKT]*

omit from the column headed "Responsible Person" (all instances): **LI** *substitute (all instances):* **JU**

[98] Schedule 1, Part 1, entry for Upadacitinib in each of the forms: Tablet 15 mg; and Tablet 30 mg *[Maximum Quantity: 28; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C13930**

(b) *omit from the column headed "Purposes":* **P13930**

[99] Schedule 1, Part 1, entry for Ustekinumab in the form Injection 90 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 1]*

(a) *omit from the column headed "Circumstances":* **C14009**

(b) *omit from the column headed "Purposes":* **P14009**

[100] Schedule 1, Part 1, entry for Valaciclovir

omit:

Valaciclovir	Tablet 500 mg (as hydrochloride)	Oral	NOUMED VALACICLOVIR	VO	MP NP	C5940 C5961		30	5	30

[101] Schedule 1, Part 1, entry for Vildagliptin in the form Tablet 50 mg *[Maximum Quantity: 60; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C6346 C6363 C6376** *substitute:* **C15261**

(b) *omit from the column headed "Purposes":* **P6346 P6363 P6376** *substitute:* **P15261**

[102] Schedule 1, Part 1, entry for Vildagliptin in the form Tablet 50 mg *[Maximum Quantity: 120; Number of Repeats: 5]*

(a) *omit from the column headed "Circumstances":* **C14978 C14999 C15000** *substitute:* **C15287**

(b) *omit from the column headed "Purposes":* **P14978 P14999 P15000** *substitute:* **P15287**

[103] Schedule 1, Part 1, entry for Vildagliptin with metformin

substitute:

Vildagliptin with metformin	Tablet containing 50 mg vildagliptin with 1000 mg metformin hydrochloride	Oral	Galvumet 50/1000	NV	MP NP	C15276	P15276	60	5	60
Vildagliptin with metformin	Tablet contaiing 50 mg vildagliptin with 1000 mg metformin hydrochloride	Oral	Galvumet 50/1000	NV	MP NP	C15288	P15288	120	5	60
Vildagliptin with metformin	Tablet containing 50 mg vildagliptin with 500 mg metformin hydrochloride	Oral	Galvumet 50/500	NV	MP NP	C15276	P15276	60	5	60
Vildagliptin with	Tablet containing 50 mg	Oral	Galvumet 50/500	NV	MP NP	C15288	P15288	120	5	60

metformin	vildagliptin with 500 mg metformin hydrochloride										
Vildagliptin with metformin	Tablet containing 50 mg vildagliptin with 850 mg metformin hydrochloride	Oral	Galvumet 50/850	NV	MP NP	C15276	P15276	60	5		60
Vildagliptin with metformin	Tablet containing 50 mg vildagliptin with 850 mg metformin hydrochloride	Oral	Galvumet 50/850	NV	MP NP	C15288	P15288	120	5		60

[104] Schedule 1, Part 1, entry for Vosoritide in each of the forms: Powder for injection 400 micrograms with diluent; Powder for injection 560 micrograms with diluent; and Powder for injection 1.2 mg with diluent

omit from the column headed "Circumstances": **C13929**

[105] Schedule 1, Part 2

insert as first entry:

Bisacodyl	Enemas 10 mg in 5 mL, 25	Rectal	Bisalax	OX	1

[106] Schedule 1, Part 2, omit entry for Insulin neutral with insulin isophane

[107] Schedule 1, Part 2, after entry for Hypromellose with dextran

insert:

Ketoconazole	Cream 20 mg per g, 30 g	Application	Nizoral 2% Cream	JT	1

[108] Schedule 1, Part 2, omit entry for Macrogol 3350

[109] Schedule 1, Part 2, omit entry for Pancrelipase

[110] Schedule 1, Part 2, omit entry for Paraffin with retinol palmitate

[111] Schedule 1, Part 2, omit entry for Raltegravir

[112] Schedule 3

omit:

LI	Luminarie Pty Ltd	18 601 868 375

[113] Schedule 3, after details relevant for Responsible Person code XY

insert:

YG	EUGIA PHARMA (AUSTRALIA) PTY LTD	57 656 083 028

[114] Schedule 3, after details relevant for Responsible Person code YN

insert:

YO	The Trustee for ORSPEC PHARMA UNIT TRUST	15 634 980 417

[115] Schedule 4, Part 1, omit entry for Circumstances Code "C4072"

[116] Schedule 4, Part 1, omit entry for Circumstances Code "C4274"

[117] Schedule 4, Part 1, omit entry for Circumstances Code "C4275"

[118] Schedule 4, Part 1, omit entry for Circumstances Code "C4349"

[119] Schedule 4, Part 1, omit entry for Circumstances Code "C4363"

[120] Schedule 4, Part 1, omit entry for Circumstances Code "C4364"

[121] Schedule 4, Part 1, omit entry for Circumstances Code "C4388"

[122] Schedule 4, Part 1, omit entry for Circumstances Code "C4423"

[123] Schedule 4, Part 1, omit entry for Circumstances Code "C4427"

[124] Schedule 4, Part 1, omit entry for Circumstances Code "C4991"

[125] Schedule 4, Part 1, omit entry for Circumstances Code "C5469"

[126] Schedule 4, Part 1, omit entry for Circumstances Code "C5478"

[127] Schedule 4, Part 1, omit entry for Circumstances Code "C5500"

[128] Schedule 4, Part 1, omit entry for Circumstances Code "C5629"

[129] Schedule 4, Part 1, omit entry for Circumstances Code "C5631"

[130] Schedule 4, Part 1, omit entry for Circumstances Code "C5657"

[131] Schedule 4, Part 1, omit entry for Circumstances Code "C5739"

[132] **Schedule 4, Part 1, omit entry for Circumstances Code "C5779"**

[133] **Schedule 4, Part 1, omit entry for Circumstances Code "C5798"**

[134] **Schedule 4, Part 1, omit entry for Circumstances Code "C5953"**

[135] **Schedule 4, Part 1, omit entry for Circumstances Code "C5966"**

[136] **Schedule 4, Part 1, omit entry for Circumstances Code "C6333"**

[137] **Schedule 4, Part 1, omit entry for Circumstances Code "C6334"**

[138] **Schedule 4, Part 1, omit entry for Circumstances Code "C6335"**

[139] **Schedule 4, Part 1, omit entry for Circumstances Code "C6336"**

[140] **Schedule 4, Part 1, omit entry for Circumstances Code "C6344"**

[141] **Schedule 4, Part 1, omit entry for Circumstances Code "C6346"**

[142] **Schedule 4, Part 1, omit entry for Circumstances Code "C6357"**

[143] **Schedule 4, Part 1, omit entry for Circumstances Code "C6363"**

[144] **Schedule 4, Part 1, omit entry for Circumstances Code "C6376"**

[145] **Schedule 4, Part 1, entry for Circumstances Code "C6434"**

omit from the column headed "Listed Drug": **Ketoconazole**

[146] **Schedule 4, Part 1, omit entry for Circumstances Code "C6443"**

[147] **Schedule 4, Part 1, omit entry for Circumstances Code "C6645"**

[148] **Schedule 4, Part 1, omit entry for Circumstances Code "C6664"**

[149] **Schedule 4, Part 1, omit entry for Circumstances Code "C7492"**

[150] **Schedule 4, Part 1, omit entry for Circumstances Code "C7495"**

[151] **Schedule 4, Part 1, omit entry for Circumstances Code "C7498"**

[152] **Schedule 4, Part 1, omit entry for Circumstances Code "C7505"**

[153] **Schedule 4, Part 1, omit entry for Circumstances Code "C7506"**

[154] **Schedule 4, Part 1, omit entry for Circumstances Code "C7507"**

[155] Schedule 4, Part 1, omit entry for Circumstances Code "C7524"

[156] Schedule 4, Part 1, omit entry for Circumstances Code "C7528"

[157] Schedule 4, Part 1, omit entry for Circumstances Code "C7530"

[158] Schedule 4, Part 1, omit entry for Circumstances Code "C7541"

[159] Schedule 4, Part 1, omit entry for Circumstances Code "C7556"

[160] Schedule 4, Part 1, omit entry for Circumstances Code "C7598"

[161] Schedule 4, Part 1, omit entry for Circumstances Code "C7629"

[162] Schedule 4, Part 1, omit entry for Circumstances Code "C7645"

[163] Schedule 4, Part 1, entry for Circumstances Code "C10742"

omit entry for Circumstances Code "C10742" and substitute:

C10742	P10742	CN10742	Guselkumab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or re-commencement 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 20 weeks of treatment under this restriction; Patient must be aged 18 years or older; 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	Compliance with Written Authority Required procedures

				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. The authority application must be made in writing and must include (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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.	

[164] Schedule 4, Part 1, entry for Circumstances Code "C11090"

omit entry for Circumstances Code "C11090" and substitute:

C11090	P11090	CN11090	Tildrakizumab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or re-commencement 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 28 weeks of treatment under this restriction; Patient must be aged 18 years or older;	Compliance with Written Authority Required procedures

				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 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 (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.	

[165] Schedule 4, Part 1, entry for Circumstances Code "C11096"

omit entry for Circumstances Code "C11096" and substitute:

C11096	P11096	CN11096	Ixekizumab Secukinumab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or re-commencement 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 aged 18 years or older; 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 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 (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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	Compliance with Written Authority Required procedures

				(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.	

[166] Schedule 4, Part 1, entry for Circumstances Code "C11119"

omit entry for Circumstances Code "C11119" and substitute:

C11119	P11119	CN11119	Ustekinumab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or re-commencement 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 28 weeks of treatment under this restriction; Patient must be aged 18 years or older; 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. 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.	Compliance with Written Authority Required procedures

				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 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. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and 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.	

[167] Schedule 4, Part 1, entry for Circumstances Code "C11123"

omit entry for Circumstances Code "C11123" and substitute:

C11123	P11123	CN11123	Tildrakizumab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or re-commencement 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	Compliance with Written Authority Required procedures

				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 28 weeks of treatment under this restriction; Patient must be aged 18 years or older; 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 PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. 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. 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 (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and 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. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 100 mg for weeks 0 and 4, then 100 mg every 12 weeks thereafter.	

[168] Schedule 4, Part 1, entry for Circumstances Code "C11130"

omit entry for Circumstances Code "C11130" and substitute:

C11130	P11130	CN11130	Guselkumab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or re-commencement 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 20 weeks of treatment under this restriction; Patient must be aged 18 years or older; 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 PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. 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	Compliance with Written Authority Required procedures

				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. The authority application must be made in writing and must include (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and 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.	

[169] Schedule 4, Part 1, entry for Circumstances Code "C11138"

omit entry for Circumstances Code "C11138" and substitute:

C11138	P11138	CN11138	Ixekizumab Secukinumab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or re-commencement 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 aged 18 years or older;	Compliance with Written Authority Required procedures

				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. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence 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 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 (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and 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.	

[170] Schedule 4, Part 1, entry for Circumstances Code "C11153"

omit entry for Circumstances Code "C11153" and substitute:

C11153	P11153	CN11153	Ustekinumab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or re-commencement 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 28 weeks of treatment under this restriction; Patient must be aged 18 years or older; 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 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. At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application -	Compliance with Written Authority Required procedures

				Supporting Information Form 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.	

[171] Schedule 4, Part 1, omit entry for Circumstances Code "C11178"

[172] Schedule 4, Part 1, omit entry for Circumstances Code "C11181"

[173] Schedule 4, Part 1, omit entry for Circumstances Code "C11183"

[174] Schedule 4, Part 1, omit entry for Circumstances Code "C11185"

[175] Schedule 4, Part 1, omit entry for Circumstances Code "C11229"

[176] Schedule 4, Part 1, entry for Circumstances Code "C11704"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[177] Schedule 4, Part 1, entry for Circumstances Code "C11711"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[178] Schedule 4, Part 1, entry for Circumstances Code "C11715"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[179] Schedule 4, Part 1, entry for Circumstances Code "C11716"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[180] Schedule 4, Part 1, entry for Circumstances Code "C11717"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[181] Schedule 4, Part 1, entry for Circumstances Code "C11761"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[182] Schedule 4, Part 1, entry for Circumstances Code "C11762"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[183] Schedule 4, Part 1, entry for Circumstances Code "C11763"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[184] Schedule 4, Part 1, entry for Circumstances Code "C11767"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[185] Schedule 4, Part 1, omit entry for Circumstances Code "C11841"

[186] Schedule 4, Part 1, omit entry for Circumstances Code "C11842"

[187] Schedule 4, Part 1, entry for Circumstances Code "C11844"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[188] Schedule 4, Part 1, entry for Circumstances Code "C11846"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[189] Schedule 4, Part 1, omit entry for Circumstances Code "C11848"

[190] Schedule 4, Part 1, entry for Circumstances Code "C11861"

omit entry for Circumstances Code "C11861" and substitute:

C11861	P11861	CN11861	Adalimumab	Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less 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; 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 3 biological medicines for this condition within this treatment cycle; AND Patient must not have 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 aged 18 years or older. 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 (1) a completed authority prescription form; 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 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	Compliance with Written Authority Required procedures

				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.	

[191] Schedule 4, Part 1, entry for Circumstances Code "C11892"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[192] Schedule 4, Part 1, entry for Circumstances Code "C11893"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[193] Schedule 4, Part 1, entry for Circumstances Code "C11897"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[194] Schedule 4, Part 1, entry for Circumstances Code "C11902"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[195] Schedule 4, Part 1, entry for Circumstances Code "C11924"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[196] Schedule 4, Part 1, entry for Circumstances Code "C11926"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[197] Schedule 4, Part 1, entry for Circumstances Code "C11945"

omit entry for Circumstances Code "C11945" and substitute:

C11945	P11945	CN11945	Tofacitinib Upadacitinib	Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in in biological medicine of less 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; 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 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 aged 18 years or older. 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) a completed authority prescription form(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	Compliance with Written Authority Required procedures

				Advice). 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. 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.	

[198] Schedule 4, Part 1, omit entry for Circumstances Code "C11950"

[199] Schedule 4, Part 1, entry for Circumstances Code "C11958"

omit entry for Circumstances Code "C11958" and substitute:

C11958	P11958	CN11958	Ixekizumab	Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less 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; 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 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised	Compliance with Written Authority Required procedures

				treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 20 weeks of treatment under this restriction; Patient must be aged 18 years or older. 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) a completed authority prescription form(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 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. 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. 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.	

[200] Schedule 4, Part 1, entry for Circumstances Code "C11964"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[201] Schedule 4, Part 1, entry for Circumstances Code "C12155"

omit entry for Circumstances Code "C12155" and substitute:

C12155	P12155	CN12155	Adalimumab	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 aged 18 years or older; 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 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	Compliance with Written Authority Required procedures

				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) a completed authority prescription form(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.	

[202] Schedule 4, Part 1, entry for Circumstances Code "C12212"

omit entry for Circumstances Code "C12212" and substitute:

C12212	P12212	CN12212	Adalimumab	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 aged 18 years or older; 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	Compliance with Written Authority Required procedures

				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 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) a completed authority prescription form(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.	

[203] Schedule 4, Part 1, entry for Circumstances Code "C12272"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**

substitute: **Compliance with Written Authority Required procedures**

[204] Schedule 4, Part 1, omit entry for Circumstances Code "C12275"

[205] Schedule 4, Part 1, omit entry for Circumstances Code "C12278"

[206] Schedule 4, Part 1, entry for Circumstances Code "C12306"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[207] Schedule 4, Part 1, entry for Circumstances Code "C12315"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[208] Schedule 4, Part 1, entry for Circumstances Code "C12399"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[209] Schedule 4, Part 1, entry for Circumstances Code "C12404"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[210] Schedule 4, Part 1, entry for Circumstances Code "C12405"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[211] Schedule 4, Part 1, entry for Circumstances Code "C12436"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[212] Schedule 4, Part 1, omit entry for Circumstances Code "C12439"

[213] Schedule 4, Part 1, entry for Circumstances Code "C12450"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[214] Schedule 4, Part 1, entry for Circumstances Code "C12451"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[215] Schedule 4, Part 1, entry for Circumstances Code "C12609"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[216] Schedule 4, Part 1, entry for Circumstances Code "C12614"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[217] Schedule 4, Part 1, omit entry for Circumstances Code "C12624"

[218] Schedule 4, Part 1, omit entry for Circumstances Code "C12625"

[219] Schedule 4, Part 1, entry for Circumstances Code "C12630"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[220] Schedule 4, Part 1, entry for Circumstances Code "C12635"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[221] Schedule 4, Part 1, entry for Circumstances Code "C12639"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[222] Schedule 4, Part 1, entry for Circumstances Code "C12672"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[223] Schedule 4, Part 1, entry for Circumstances Code "C12676"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**

substitute: **Compliance with Written Authority Required procedures**

[224] Schedule 4, Part 1, entry for Circumstances Code "C12703"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[225] Schedule 4, Part 1, entry for Circumstances Code "C12704"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[226] Schedule 4, Part 1, entry for Circumstances Code "C12705"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[227] Schedule 4, Part 1, entry for Circumstances Code "C12711"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[228] Schedule 4, Part 1, entry for Circumstances Code "C12712"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[229] Schedule 4, Part 1, entry for Circumstances Code "C12713"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[230] Schedule 4, Part 1, entry for Circumstances Code "C12721"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[231] Schedule 4, Part 1, entry for Circumstances Code "C12722"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[232] Schedule 4, Part 1, entry for Circumstances Code "C12723"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[233] Schedule 4, Part 1, entry for Circumstances Code "C12725"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[234] Schedule 4, Part 1, entry for Circumstances Code "C12726"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[235] Schedule 4, Part 1, entry for Circumstances Code "C12731"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[236] Schedule 4, Part 1, entry for Circumstances Code "C12738"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[237] Schedule 4, Part 1, entry for Circumstances Code "C12749"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[238] Schedule 4, Part 1, entry for Circumstances Code "C12752"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[239] Schedule 4, Part 1, entry for Circumstances Code "C12755"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[240] Schedule 4, Part 1, entry for Circumstances Code "C12758"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**

substitute: **Compliance with Written Authority Required procedures**

[241] Schedule 4, Part 1, entry for Circumstances Code "C12760"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[242] Schedule 4, Part 1, entry for Circumstances Code "C12765"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[243] Schedule 4, Part 1, entry for Circumstances Code "C12768"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[244] Schedule 4, Part 1, entry for Circumstances Code "C12769"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[245] Schedule 4, Part 1, entry for Circumstances Code "C12770"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[246] Schedule 4, Part 1, entry for Circumstances Code "C12771"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[247] Schedule 4, Part 1, entry for Circumstances Code "C12774"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[248] Schedule 4, Part 1, entry for Circumstances Code "C12775"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[249] Schedule 4, Part 1, entry for Circumstances Code "C12779"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[250] Schedule 4, Part 1, entry for Circumstances Code "C12780"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[251] Schedule 4, Part 1, entry for Circumstances Code "C12784"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[252] Schedule 4, Part 1, entry for Circumstances Code "C12785"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[253] Schedule 4, Part 1, entry for Circumstances Code "C12789"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[254] Schedule 4, Part 1, entry for Circumstances Code "C12790"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[255] Schedule 4, Part 1, entry for Circumstances Code "C12791"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[256] Schedule 4, Part 1, entry for Circumstances Code "C12793"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[257] Schedule 4, Part 1, entry for Circumstances Code "C12798"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**

substitute: **Compliance with Written Authority Required procedures**

[258] Schedule 4, Part 1, entry for Circumstances Code "C12803"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[259] Schedule 4, Part 1, entry for Circumstances Code "C12805"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[260] Schedule 4, Part 1, entry for Circumstances Code "C12806"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[261] Schedule 4, Part 1, entry for Circumstances Code "C12809"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[262] Schedule 4, Part 1, entry for Circumstances Code "C12810"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[263] Schedule 4, Part 1, entry for Circumstances Code "C12812"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[264] Schedule 4, Part 1, entry for Circumstances Code "C12817"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[265] Schedule 4, Part 1, entry for Circumstances Code "C12820"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[266] Schedule 4, Part 1, entry for Circumstances Code "C12824"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[267] Schedule 4, Part 1, entry for Circumstances Code "C12826"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[268] Schedule 4, Part 1, entry for Circumstances Code "C12829"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[269] Schedule 4, Part 1, entry for Circumstances Code "C12831"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[270] Schedule 4, Part 1, entry for Circumstances Code "C12832"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[271] Schedule 4, Part 1, entry for Circumstances Code "C12834"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[272] Schedule 4, Part 1, entry for Circumstances Code "C12855"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[273] Schedule 4, Part 1, entry for Circumstances Code "C12857"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[274] Schedule 4, Part 1, entry for Circumstances Code "C12858"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[275] Schedule 4, Part 1, entry for Circumstances Code "C12860"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[276] Schedule 4, Part 1, entry for Circumstances Code "C12861"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[277] Schedule 4, Part 1, entry for Circumstances Code "C12866"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[278] Schedule 4, Part 1, entry for Circumstances Code "C12867"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[279] Schedule 4, Part 1, entry for Circumstances Code "C12869"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[280] Schedule 4, Part 1, entry for Circumstances Code "C12671"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[281] Schedule 4, Part 1, entry for Circumstances Code "C12772"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[282] Schedule 4, Part 1, entry for Circumstances Code "C12876"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[283] Schedule 4, Part 1, entry for Circumstances Code "C12877"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**

substitute: **Compliance with Written Authority Required procedures**

[284] Schedule 4, Part 1, entry for Circumstances Code "C12880"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[285] Schedule 4, Part 1, entry for Circumstances Code "C12882"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[286] Schedule 4, Part 1, entry for Circumstances Code "C12884"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[287] Schedule 4, Part 1, entry for Circumstances Code "C12886"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[288] Schedule 4, Part 1, entry for Circumstances Code "C12887"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[289] Schedule 4, Part 1, entry for Circumstances Code "C12899"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[290] Schedule 4, Part 1, omit entry for Circumstances Code "C12983"

[291] Schedule 4, Part 1, omit entry for Circumstances Code "C12986"

[292] Schedule 4, Part 1, omit entry for Circumstances Code "C13010"

[293] Schedule 4, Part 1, omit entry for Circumstances Code "C13011"

[294] Schedule 4, Part 1, omit entry for Circumstances Code "C13012"

[295] Schedule 4, Part 1, omit entry for Circumstances Code "C13015"

[296] **Schedule 4, Part 1, omit entry for Circumstances Code "C13029"**

[297] **Schedule 4, Part 1, entry for Circumstances Code "C13177"**

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[298] **Schedule 4, Part 1, entry for Circumstances Code "C13184"**

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[299] **Schedule 4, Part 1, entry for Circumstances Code "C13233"**

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[300] **Schedule 4, Part 1, entry for Circumstances Code "C13250"**

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[301] **Schedule 4, Part 1, omit entry for Circumstances Code "C13327"**

[302] **Schedule 4, Part 1, omit entry for Circumstances Code "C13377"**

[303] **Schedule 4, Part 1, omit entry for Circumstances Code "C13491"**

[304] **Schedule 4, Part 1, omit entry for Circumstances Code "C13496"**

[305] **Schedule 4, Part 1, omit entry for Circumstances Code "C13497"**

[306] **Schedule 4, Part 1, omit entry for Circumstances Code "C13499"**

[307] **Schedule 4, Part 1, omit entry for Circumstances Code "C13500"**

[308] **Schedule 4, Part 1, omit entry for Circumstances Code "C13502"**

[309] **Schedule 4, Part 1, omit entry for Circumstances Code "C13505"**

[310] **Schedule 4, Part 1, omit entry for Circumstances Code "C13506"**

[311] **Schedule 4, Part 1, omit entry for Circumstances Code "C13510"**

[312] **Schedule 4, Part 1, omit entry for Circumstances Code "C13512"**

[313] Schedule 4, Part 1, omit entry for Circumstances Code "C13514"

[314] Schedule 4, Part 1, omit entry for Circumstances Code "C13515"

[315] Schedule 4, Part 1, omit entry for Circumstances Code "C13575"

[316] Schedule 4, Part 1, omit entry for Circumstances Code "C13576"

[317] Schedule 4, Part 1, omit entry for Circumstances Code "C13577"

[318] Schedule 4, Part 1, omit entry for Circumstances Code "C13582"

[319] Schedule 4, Part 1, entry for Circumstances Code "C13598"

omit entry for Circumstances Code "C13598" and substitute:

C13598	P13598	CN13598	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 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. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing	Compliance with Written Authority Required procedures

				treatment restrictions, 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 from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. 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 (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and 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.	

[320] Schedule 4, Part 1, entry for Circumstances Code "C13629"

omit from the column headed "Authority Requirements (part of Circumstances; or Conditions)": **Compliance with Authority Required procedures**
substitute: **Compliance with Written Authority Required procedures**

[321] Schedule 4, Part 1, omit entry for Circumstances Code "C13631"

[322] Schedule 4, Part 1, omit entry for Circumstances Code "C13634"

[323] Schedule 4, Part 1, entry for Circumstances Code "C13646"

omit entry for Circumstances Code "C13646" and substitute:

C13646	P13646	CN13646	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. Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, 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 from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe. 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.	Compliance with Written Authority Required procedures

				The authority application must be made in writing and must include (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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.	

[324] Schedule 4, Part 1, entry for Circumstances Code "C13692"

omit entry for Circumstances Code "C13692" and substitute:

C13692	P13692	CN13692	Infliximab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or re-commencement 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 22 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	Compliance with Written Authority Required procedures

				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. 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. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form 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.	

[325] Schedule 4, Part 1, entry for Circumstances Code "C13719"

omit entry for Circumstances Code "C13719" and substitute:

C13719	P13719	CN13719	Infliximab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or re-commencement 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	Compliance with Written Authority Required procedures

				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 22 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. 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. At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised. The authority application must be made in writing and must include (a) a completed authority prescription form(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and 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.	

[326] Schedule 4, Part 1, omit entry for Circumstances Code "C13852"

[327] Schedule 4, Part 1, omit entry for Circumstances Code "C13863"

[328] Schedule 4, Part 1, omit entry for Circumstances Code "C13864"

[329] Schedule 4, Part 1, omit entry for Circumstances Code "C13865"

[330] Schedule 4, Part 1, omit entry for Circumstances Code "C13866"

[331] Schedule 4, Part 1, omit entry for Circumstances Code "C13877"

[332] Schedule 4, Part 1, omit entry for Circumstances Code "C13890"

[333] Schedule 4, Part 1, omit entry for Circumstances Code "C13891"

[334] Schedule 4, Part 1, omit entry for Circumstances Code "C13929"

[335] Schedule 4, Part 1, omit entry for Circumstances Code "C13930"

[336] Schedule 4, Part 1, omit entry for Circumstances Code "C13986"

[337] Schedule 4, Part 1, omit entry for Circumstances Code "C13993"

[338] Schedule 4, Part 1, omit entry for Circumstances Code "C14007"

[339] Schedule 4, Part 1, omit entry for Circumstances Code "C14009"

[340] Schedule 4, Part 1, omit entry for Circumstances Code "C14054"

[341] Schedule 4, Part 1, omit entry for Circumstances Code "C14101"

[342] Schedule 4, Part 1, omit entry for Circumstances Code "C14126"

[343] Schedule 4, Part 1, omit entry for Circumstances Code "C14127"

[344] Schedule 4, Part 1, omit entry for Circumstances Code "C14129"

[345] Schedule 4, Part 1, omit entry for Circumstances Code "C14130"

[346] Schedule 4, Part 1, omit entry for Circumstances Code "C14131"

[347] Schedule 4, Part 1, omit entry for Circumstances Code "C14132"

[348] Schedule 4, Part 1, entry for Circumstances Code "C14370"

omit entry for Circumstances Code "C14370" and substitute:

C14370	P14370	CN14370	Nusinersen	Spinal muscular atrophy (SMA) Changing the prescribed therapy Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19th birthday; AND Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; or Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment; AND Patient must be untreated with gene therapy; AND Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.	Compliance with Authority Required procedures

[349] Schedule 4, Part 1, omit entry for Circumstances Code "C14384"

[350] Schedule 4, Part 1, entry for Circumstances Code "C14396"

omit entry for Circumstances Code "C14396" and substitute:

C14396	P14396	CN14396	Bimekizumab	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	Compliance with Written Authority Required procedures

				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 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 PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. 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. 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) a completed authority prescription form(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.	

[351] Schedule 4, Part 1, omit entry for Circumstances Code "C14417"

[352] Schedule 4, Part 1, entry for Circumstances Code "C14421"

omit entry for Circumstances Code "C14421" and substitute:

C14421	P14421	CN14421	Nusinersen	Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA) Changing the prescribed therapy Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19th birthday for SMA type IIIB/IIIC; AND Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; or Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA; AND Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment; AND Patient must be untreated with gene therapy; AND Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.	Compliance with Authority Required procedures

[353] Schedule 4, Part 1, entry for Circumstances Code "C14437"

omit entry for Circumstances Code "C14437" and substitute:

C14437	P14437	CN14437	Bimekizumab	Severe chronic plaque psoriasis	Compliance with Written

				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 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 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 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) a completed authority prescription form(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	Authority Required procedures

				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.	

[354] Schedule 4, Part 1, omit entry for Circumstances Code "C14523"

[355] Schedule 4, Part 1, omit entry for Circumstances Code "C14524"

[356] Schedule 4, Part 1, omit entry for Circumstances Code "C14555"

[357] Schedule 4, Part 1, omit entry for Circumstances Code "C14617"

[358] Schedule 4, Part 1, omit entry for Circumstances Code "C14858"

[359] Schedule 4, Part 1, omit entry for Circumstances Code "C14859"

[360] Schedule 4, Part 1, omit entry for Circumstances Code "C14862"

[361] Schedule 4, Part 1, omit entry for Circumstances Code "C14876"

[362] Schedule 4, Part 1, omit entry for Circumstances Code "C14878"

[363] Schedule 4, Part 1, omit entry for Circumstances Code "C14881"

[364] Schedule 4, Part 1, omit entry for Circumstances Code "C14885"

[365] Schedule 4, Part 1, omit entry for Circumstances Code "C14887"

[366] Schedule 4, Part 1, omit entry for Circumstances Code "C14888"

[367] Schedule 4, Part 1, omit entry for Circumstances Code "C14891"

[368] Schedule 4, Part 1, omit entry for Circumstances Code "C14894"

[369] Schedule 4, Part 1, omit entry for Circumstances Code "C14905"

[370] Schedule 4, Part 1, omit entry for Circumstances Code "C14911"

[371] Schedule 4, Part 1, omit entry for Circumstances Code "C14924"

[372] Schedule 4, Part 1, omit entry for Circumstances Code "C14925"

[373] Schedule 4, Part 1, omit entry for Circumstances Code "C14933"

[374] Schedule 4, Part 1, omit entry for Circumstances Code "C14935"

[375] Schedule 4, Part 1, omit entry for Circumstances Code "C14937"

[376] Schedule 4, Part 1, omit entry for Circumstances Code "C14949"

[377] Schedule 4, Part 1, omit entry for Circumstances Code "C14950"

[378] Schedule 4, Part 1, omit entry for Circumstances Code "C14954"

[379] Schedule 4, Part 1, omit entry for Circumstances Code "C14974"

[380] Schedule 4, Part 1, omit entry for Circumstances Code "C14978"

[381] Schedule 4, Part 1, omit entry for Circumstances Code "C14987"

[382] Schedule 4, Part 1, omit entry for Circumstances Code "C14999"

[383] Schedule 4, Part 1, omit entry for Circumstances Code "C15000"

[384] Schedule 4, Part 1, omit entry for Circumstances Code "C15001"

[385] Schedule 4, Part 1, omit entry for Circumstances Code "C15002"

[386] Schedule 4, Part 1, omit entry for Circumstances Code "C15014"

[387] Schedule 4, Part 1, entry for Circumstances Code "C15069"

omit entry for Circumstances Code "C15069" and substitute:

C15069	P15069	CN15069	Nusinersen	Spinal muscular atrophy (SMA) Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA (1 or 2 copies of the SMN2 gene) listing Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND	Compliance with Authority Required procedures

				Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; or Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition; AND The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND The treatment must be given concomitantly with best supportive care for this condition; AND The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug; Patient must have been 18 years of age or younger at the time of initial treatment with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.	

[388] Schedule 4, Part 1, omit entry for Circumstances Code "C15088"

[389] Schedule 4, Part 1, entry for Circumstances Code "C15095"

omit entry for Circumstances Code "C15095" and substitute:

C15095	P15095	CN15095	Risdiplam	Spinal muscular atrophy (SMA) Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA (1 or 2 copies of the SMN2 gene) Patient must have previously received PBS-subsidised treatment with this drug for this condition; or Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition; AND The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition; AND The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug; AND The treatment must be given concomitantly with best supportive care for this condition; AND	Compliance with Authority Required procedures

				Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic; AND Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy; Patient must have been 18 years of age or younger at the time of initial treatment with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required. The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing. The approved Product Information recommended dosing is as follows (i) 16 days to less than 2 months of age 0.15 mg/kg (ii) 2 months to less than 2 years of age 0.20 mg/kg (iii) 2 years of age and older weighing less than 20 kg 0.25 mg/kg (iv) 2 years of age and older weighing 20 kg or more 5 mg In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to 1 unit where (i) applies; 2 units where (ii) applies; 3 units where (iii) applies; 3 units where (iv) applies.	

[390] Schedule 4, Part 1, entry for Circumstances Code "C15112"

omit entry for Circumstances Code "C15112" and substitute:

C15112	P15112	CN15112	Nusinersen	Spinal muscular atrophy (SMA) Continuing/maintenance treatment of a patient commenced on this drug under the pre-symptomatic SMA (3 copies of the SMN2 gene) listing Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of	Compliance with Authority Required procedures

				SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; AND Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; or Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition; AND The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition; AND The treatment must be given concomitantly with best supportive care for this condition; AND The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug; Patient must have been 18 years of age or younger at the time of initial treatment with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day. In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.	

[391] Schedule 4, Part 1, omit entry for Circumstances Code "C15122"

[392] Schedule 4, Part 1, omit entry for Circumstances Code "C15132"

[393] Schedule 4, Part 1, omit entry for Circumstances Code "C15144"

[394] Schedule 4, Part 1, omit entry for Circumstances Code "C15153"

[395] Schedule 4, Part 1, entry for Circumstances Code "C15213"

omit entry for Circumstances Code "C15213" and substitute:

C15213	P15213	CN15213	Risankizumab	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	Compliance with Written Authority Required procedures

				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 28 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 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) a completed authority prescription form(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. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.	

[396] Schedule 4, Part 1, entry for Circumstances Code "C15222"

omit entry for Circumstances Code "C15222" and substitute:

C15222	P15222	CN15222	Risankizumab	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 28 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 PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. 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	Compliance with Written Authority Required procedures

				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. The authority application must be made in writing and must include: (1) a completed authority prescription form(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. At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.	

[397] Schedule 4, Part 1, after entry for Circumstances Code "C15242"

insert:

C15249	P15249	CN15249	Adalimumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 1 (new patient) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this	Compliance with Written Authority Required procedures

				drug for this condition; OR Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. 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. At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient) or Initial 2 (recommencement of treatment) - balance of supply The authority application must be made in writing and must include: (1) a completed authority prescription form; 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: (i) the Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any	

				courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics.	
C15257	P15257	CN15257	Osimertinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment of second-line EGFR tyrosine kinase inhibitor therapy The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Patient must be undergoing continuing treatment with this drug as second-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed). PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (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
C15261	P15261	CN15261	Alogliptin Linagliptin Saxagliptin Sitagliptin Vildagliptin	Diabetes mellitus type 2 The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin; AND The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15261
C15263	P15263	CN15263	Dulaglutide Semaglutide	Diabetes mellitus type 2 Subsequent PBS-prescriptions for any GLP-1 receptor agonist Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.	Compliance with Authority Required procedures - Streamlined Authority Code 15263
C15265	P15265	CN15265	Dapagliflozin Empagliflozin	Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin; AND The condition must be inadequately responsive to at least one of: metformin, a	Compliance with Authority Required procedures - Streamlined Authority Code 15265

				sulfonylurea, insulin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.	
C15267	P15267	CN15267	Dapagliflozin with metformin Empagliflozin with metformin	Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be inadequately responsive to metformin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15267
C15269	C15269	CN15269	Empagliflozin with linagliptin Saxagliptin with dapagliflozin	Diabetes mellitus type 2 The treatment must be in combination with at least metformin; AND The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15269
C15270	C15270	CN15270	Empagliflozin with linagliptin Saxagliptin with dapagliflozin	Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with at least metformin; AND The condition must be inadequately responsive to dual therapy consisting of metformin with either: a DDP-4 inhibitor, an SGLT2 inhibitor. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor, another DPP4 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15270
C15276	P15276	CN15276	Alogliptin with metformin Linagliptin with metformin Saxagliptin with metformin Sitagliptin with metformin Vildagliptin with metformin	Diabetes mellitus type 2 The condition must be inadequately responsive to metformin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15276
C15279	P15279	CN15279	Secukinumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND	Compliance with Written Authority Required procedures

				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 Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 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. The authority application must be made in writing and must include: (1) two completed authority prescription forms; 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: (i) the Hurley stage grading; and (ii) the AN count. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. 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.	
C15280	P15280	CN1528	Secukinumab	Moderate to severe hidradenitis suppurativa	Compliance with Written Authority Required

				Initial treatment - Initial 1 (new patient) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 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. The authority application must be made in writing and must include: (1) two completed authority prescription forms; 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: (i) the Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a	procedures

				three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics. This restriction is intended for induction dosing only. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. 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.	
C15281	P15281	CN15281	Osimertinib	Stage IB, II or IIIA non-small cell lung cancer Adjuvant therapy Patient must be both: (i) initiating treatment, (ii) untreated with EGFR-TKI for non small cell lung cancer; OR Patient must be continuing existing PBS-subsidised treatment with this drug; OR Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) untreated with EGFR-TKI at the time this drug was initiated. The treatment must be for the purpose of adjuvant therapy following surgical resection; AND Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material; AND Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be commenced within 26 weeks of surgery; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 3 years in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the word 'cancelled'; where (i)/(ii) has occurred. PBS-subsidised treatment with this drug is restricted to one line of therapy at any	Compliance with Authority Required procedures

				disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15283	P15283	CN15283	Osimertinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment of first-line EGFR tyrosine kinase inhibitor therapy The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. Patient must be undergoing continuing treatment with this drug as first-line therapy (i.e. there are 2 Continuing treatment listings for this drug - ensure the correct Continuing treatment restriction is being accessed). PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (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
C15287	P15287	CN15287	Alogliptin Linagliptin Saxagliptin Sitagliptin Vildagliptin	Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin; AND The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15287
C15288	P15288	CN15288	Alogliptin with metformin Linagliptin with metformin Saxagliptin with metformin Sitagliptin with metformin Vildagliptin with metformin	Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be inadequately responsive to metformin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another DPP4 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15288
C15289	P15289	CN15289	Dapagliflozin with metformin Empagliflozin with metformin	Diabetes mellitus type 2 The condition must be inadequately responsive to metformin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15289

C15290	P15290	CN15290	Pioglitazone	Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.	
C15295	P15295	CN15295	Secukinumab	Moderate to severe hidradenitis suppurativa 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 2 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. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. 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 16 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. The authority application must be made in writing and must include: (1) two completed authority prescription forms; 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	Compliance with Written Authority Required procedures

				Advice) which includes: (i) the Hurley stage grading; and (ii) the AN count. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. 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.	
C15296	P15296	CN15296	Secukinumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND 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 Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 16 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	Compliance with Written Authority Required procedures

				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) two completed authority prescription forms; 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: (i) the Hurley stage grading; and (ii) the AN count. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. This restriction is intended for induction dosing only. 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.	
C15299	P15299	CN15299	Osimertinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment as first-line epidermal growth factor receptor tyrosine kinase inhibitor therapy The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have a WHO performance status of 2 or less; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have received previous PBS-subsidised treatment with another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI); OR Patient must have developed intolerance to another epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal. Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors. PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease,	Compliance with Authority Required procedures

				subsidy under locally advanced or metastatic disease is no longer available).	
C15301	P15301	CN15301	Dulaglutide Semaglutide	Diabetes mellitus type 2 First PBS-prescription for this drug The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin; AND The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin; AND Patient must not have achieved a clinically meaningful glycaemic response with an SGLT2 inhibitor; OR Patient must have a contraindication/intolerance requiring treatment discontinuation of an SGLT2 inhibitor. Patient must not be undergoing concomitant PBS-subsidised treatment for type 2 diabetes mellitus with any of: an SGLT2 inhibitor, a DPP4 inhibitor, another GLP-1 receptor agonist.	Compliance with Authority Required procedures
C15303	P15303	CN15303	Tafamidis	Transthyretin amyloid cardiomyopathy Second and subsequent PBS-subsidised prescriptions for this drug Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have an estimated glomerular filtration rate (eGFR) greater than 25 mL/minute/1.73 m^2; AND The treatment must be ceased where the patient's heart failure has worsened to persistent New York Heart Association (NYHA) Class III/IV heart failure; AND The treatment must be ceased where the patient has received any of: (i) a heart transplant, (ii) a liver transplant, (iii) an implanted ventricular assist device. Must be treated by a medical practitioner who is any of the following: (i) a cardiologist, (ii) a consultant physician with experience in the management of amyloid disorders; this authority application must be sought by the same medical practitioner providing treatment. Confirm whether heart failure has worsened to NYHA Class III/IV since the last authority application (yes/no). If 'no', continued PBS subsidy is available. If 'yes', continued PBS subsidy is available, but the prescriber must undertake a review of the patient within 3 months to determine whether the worsening heart failure was transient or persistent. Where this subsequent clinical review finds that the heart failure persists as NYHA Class III/IV heart failure despite active treatment with this drug, then PBS subsidy is not available.	Compliance with Authority Required procedures

				If heart failure has worsened to NYHA Class III/IV since the last authority application, no more than 2 repeat prescriptions must be prescribed.	
C15307	P15307	CN15307	Secukinumab	Moderate to severe hidradenitis suppurativa 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 2 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. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. 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 16 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. The authority application must be made in writing and must include: (1) two completed authority prescription forms; 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: (i) the Hurley stage grading; and	Compliance with Written Authority Required procedures

				(ii) the AN count. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg and 3 repeats. This restriction is intended for induction dosing only. 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.	
C15309	P15309	CN15309	Adalimumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND 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 Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. 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	Compliance with Written Authority Required procedures

				patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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: (i) the Hurley stage grading; and (ii) the AN count. 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.	
C15310	P15310	CN15310	Osimertinib	Stage IB, II or IIIA non-small cell lung cancer Adjuvant therapy Patient must be continuing existing PBS-subsidised treatment with this drug; OR Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) untreated with EGFR-TKI at the time this drug was initiated. The treatment must be for the purpose of adjuvant therapy following surgical resection; AND Patient must have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation known to confer sensitivity to treatment with EGFR tyrosine kinase inhibitors in tumour material; AND Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be commenced within 26 weeks of surgery; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 3 years in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the word 'cancelled'; where (i)/(ii) has occurred. PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease,	Compliance with Authority Required procedures

				subsidy under locally advanced or metastatic disease is no longer available).	
C15311	P15311	CN15311	Dapagliflozin Empagliflozin	Diabetes mellitus type 2 The treatment must be used in combination with at least one of: metformin, a sulfonylurea, insulin; AND The condition must be inadequately responsive to at least one of: metformin, a sulfonylurea, insulin. Patient must not be undergoing concomitant PBS-subsidised treatment with any of: a GLP-1 receptor agonist, another SGLT2 inhibitor.	Compliance with Authority Required procedures - Streamlined Authority Code 15311
C15313	P15313	CN15313	Inclisiran	Familial heterozygous hypercholesterolaemia Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2024; AND The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6 prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS-subsidised treatment with this drug for this condition was initiated; OR Patient must have had an LDL cholesterol level in excess of 5 millimoles per litre at the time non-PBS-subsidised treatment with this drug for this condition was initiated; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR	Compliance with Authority Required procedures

				Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication. Must be treated by a specialist physician; OR Must be treated by a physician who has consulted a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless	

				there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal. In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. The following must be stated at the time of application and documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.	
C15315	P15315	CN15315	Inclisiran	Familial heterozygous hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6; AND Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease; OR Patient must have an LDL cholesterol level in excess of 5 millimoles per litre; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least	Compliance with Authority Required procedures

				12 consecutive weeks in conjunction with dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication. Must be treated by a specialist physician; OR Must be treated by a physician who has consulted a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle	

				symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal. In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. The following must be stated at the time of application and documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.	
C15316	P15316	CN15316	Secukinumab	Moderate to severe hidradenitis suppurativa Initial treatment - Initial 1 (new patient) Patient must have, at the time of application, a Hurley stage II or III grading with an abscess and inflammatory nodule (AN) count greater than or equal to 3; AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of PBS subsidised treatment with this drug for this condition; OR Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of	Compliance with Written Authority Required procedures

				PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of PBS-subsidised treatment with this drug for this condition; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of application. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 16 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. The authority application must be made in writing and must include: (1) two completed authority prescription forms; 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: (i) the Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be for the induction doses, containing a quantity of 8 doses of 150 mg and no repeats and the second prescription should be for 2 doses of 150 mg	

				and 3 repeats. 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.	
C15317	P15317	CN15317	Secukinumab	Moderate to severe hidradenitis suppurativa Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 June 2024; AND Patient must have had a Hurley stage II or III with an abscess and inflammatory nodule (AN) count greater than or equal to 3 prior to starting treatment with this drug for this condition; AND Patient must have demonstrated a response to treatment by achieving Hidradenitis Suppurativa Clinical Response (HiSCR) after 12 weeks of treatment if the patient has been treated with this drug for this condition for 12 weeks or longer; AND Patient must have failed to achieve an adequate response to 2 courses of different antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had an adverse reaction to an antibiotic of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with an antibiotic due to an allergic reaction of a severity necessitating permanent treatment withdrawal resulting in the patient being unable to complete treatment with 2 different courses of antibiotics each for 3 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. 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	Compliance with Written Authority Required procedures

				patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Assessment of disease severity must not have been more than 4 weeks old at the time treatment with this drug was initiated. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) 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: (i) the Hurley stage grading; and (ii) the AN count; and (iii) the name of the antibiotic/s received for two separate courses each of three months; or (iv) confirmation that the adverse reaction or allergy to an antibiotic necessitated permanent treatment withdrawal resulting in the patient being unable to complete a three month course of antibiotics. The name of the one course of antibiotics of three months duration must be provided. Where the patient is unable to be treated with any courses of antibiotics the prescriber must confirm that the patient has a history of adverse reaction or allergy necessitating permanent treatment withdrawal to two different antibiotics (v) the Hidradenitis Suppurativa Clinical Response (HiSCR) result if the patient has received 12 weeks or more of treatment. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.	
C15319	P15319	CN15319	Adalimumab	Moderate to severe hidradenitis suppurativa 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 2 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. Must be treated by a dermatologist. Assessment of disease severity must be no more than 4 weeks old at the time of	Compliance with Written Authority Required procedures

				application. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. 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. 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. At the time of authority application the prescriber must request the first 4 weeks of treatment under this restriction; and weeks 5 to 16 of treatment under Initial 1 (new patient), Initial 2 (Change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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: (i) the Hurley stage grading; and (ii) the AN count. 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.	
C15321	P15321	CN15321	Pioglitazone	Diabetes mellitus type 2	

C15323	P15323	CN15323	Inclisiran	Non-familial hypercholesterolaemia Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2024; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have had symptomatic atherosclerotic cardiovascular disease prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had an LDL cholesterol level in excess of 1.8 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories) prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had diabetes mellitus with microalbuminuria prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had diabetes mellitus and be aged 60 years of more prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus that was present prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had a Thrombolysis in Myocardial Infarction (TIMI) Risk Score for Secondary Prevention of 4 or higher prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor	Compliance with Authority Required procedures

				(statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication. Must be treated by a specialist physician; OR Must be treated by a physician who has consulted a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times	

				the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal. In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event: (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years or more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher. A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.	

C15325	P15325	CN15325	Secukinumab	Moderate to severe hidradenitis suppurativa Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated a response to treatment with this drug for this condition. Must be treated by a dermatologist. A response to treatment is defined as: Achieving Hidradenitis Suppurativa Clinical Response (HiSCR) of a 50% reduction in AN count compared to baseline with no increase in abscesses or draining fistulae. 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. A maximum of 24 weeks treatment will be authorised under this restriction per continuing treatment. The authority application must be made in writing and must include: (1) a completed authority prescription form; 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 Hidradenitis Suppurativa Clinical Response (HiSCR) result.	Compliance with Written Authority Required procedures
C15326	P15326	CN15326	Apremilast	Severe chronic plaque psoriasis Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; AND The condition must have caused significant interference with quality of life; AND Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) deucravacitinib. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR	Compliance with Authority Required procedures - Streamlined Authority Code 15326

				Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; OR Must be treated by a general practitioner where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types. Patient must be at least 18 years of age. For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'. This assessment must be documented in the patient's medical records.	
C15328	P15328	CN15328	Secukinumab	Moderate to severe hidradenitis suppurativa Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (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 (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 (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 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment. Must be treated by a dermatologist.	Compliance with Authority Required procedures
C15329	P15329	CN15329	Osimertinib	Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment as second-line EGFR tyrosine kinase inhibitor therapy Patient must not have previously received this drug for this condition; AND The treatment must be as monotherapy; AND Patient must have a WHO performance status of 2 or less; AND The condition must have progressed on or after prior epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) therapy as first line treatment for this condition; AND Patient must have evidence of EGFR T790M mutation in tumour material at the point of progression on or after first line EGFR TKI treatment.	Compliance with Authority Required procedures

				PBS-subsidised treatment with this drug is restricted to one line of therapy at any disease staging for NSCLC (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C15330	P15330	CN15330	Deucravacitinib	Severe chronic plaque psoriasis Patient must not have achieved adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; AND The condition must have caused significant interference with quality of life; AND Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin, (iii) apremilast. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar; OR Must be treated by a general practitioner where there is agreement to continue treatment (not initiate treatment) with one of the above practitioner types. Patient must be at least 18 years of age. For patients who do not demonstrate an adequate response to apremilast, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'. This assessment must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 15330
C15331	P15331	CN15331	Inclisiran	Non-familial hypercholesterolaemia Initial treatment The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have symptomatic atherosclerotic cardiovascular disease; AND Patient must have an LDL cholesterol level in excess of 1.8 millimoles per litre; AND Patient must have atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); OR Patient must have severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; OR	Compliance with Authority Required procedures

				Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; OR Patient must have diabetes mellitus with microalbuminuria; OR Patient must have diabetes mellitus and be aged 60 years or more; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus; OR Patient must have a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse events necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise; OR Patient must have developed clinically important product-related adverse event/contraindication as defined in the TGA approved Product Information necessitating withdrawal of ezetimibe; AND Patient must not be receiving concomitant PBS-subsidised treatment with a monoclonal antibody inhibiting proprotein convertase subtilisin kexin type 9 (PCSK9) for this PBS indication. Must be treated by a specialist physician; OR Must be treated by a physician who has consulted a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater	

				stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events) must be stated at the time of application, documented in the patient's medical records and must be no more than 8 weeks old. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin results in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must be treated with the alternative statin (atorvastatin or rosuvastatin) unless there is a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should occur after a washout period of at least 4 weeks, or if the creatine kinase (CK) level is elevated, retrial should not occur until CK has returned to normal. In the event of a trial of the alternative statin, it is recommended that the patient is started with the minimum dose of statin in conjunction with ezetimibe. The dose of the alternative statin should be increased not more often than every 4 weeks until the recommended or maximum tolerated dose has been reached or target LDL-c has been achieved. One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event: (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or	

				(ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years or more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher.	

[398] Schedule 4, Part 2, after entry for Variation Code V15025

insert:

V15303	Tafamidis	If heart failure has worsened to NYHA Class III/IV since the last authority application, no more than 2 repeat prescriptions must be prescribed.

[399] Schedule 5, entry for Abacavir with lamivudine

substitute:

Abacavir with lamivudine	GRP-21981	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	Oral	ABACAVIR/LAMIVUDINE 600/300 SUN Abacavir/Lamivudine Mylan Abacavir/Lamivudine Viatris Kivexa

[400] Schedule 5, entry for Ambrisentan in the form Tablet 5 mg

omit from the column headed "Brand": **Ambrisentan Mylan**

[401] Schedule 5, entry for Amoxicillin in the form Capsule 500 mg (as trihydrate)

omit from the column headed "Schedule Equivalent Group": **GRP- 20241** *substitute:* **GRP-20241**

[402] Schedule 5, entry for Anastrozole

omit from the column headed "Brand": **Arimidex**

[403] Schedule 5, entry for Azacitidine

insert in alphabetical order in the column headed "Brand": **AZACITIDINE EUGIA**

[404] Schedule 5, entry for Benzathine benzylpenicillin in the form Powder for injection 1,200,000 units with diluent 5 mL (S19A)

insert in alphabetical order in the column headed "Brand": **Extencilline Benzathine Benzylpenicillin (France)**

[405] Schedule 5, entry for Bosentan in each of the forms: Tablet 125 mg (as monohydrate); and Tablet 62.5 mg (as monohydrate)

omit from the column headed "Brand": **Tracleer**

[406] Schedule 5, omit entry for Cefepime

[407] Schedule 5, entry for Ceftriaxone

substitute:

Ceftriaxone	GRP-21683	Powder for injection 2 g (as sodium)	Injection	Ceftriaxone Alphapharm Ceftriaxone Viatris

[408] Schedule 5, entry for Dicloxacillin in the form Capsule 250 mg (as sodium)

insert in alphabetical order in the column headed "Brand": **DICLOXACILLIN VIATRIS 250**

[409] Schedule 5, entry for Dosulepin in the form Capsule containing dosulepin hydrochloride 25 mg

omit from the column headed "Brand": **Dosulepin Mylan**

[410] Schedule 5, entry for Enalapril in the form Tablet containing enalapril maleate 10 mg

omit from the column headed "Brand": **Enalapril generichealth**

[411] Schedule 5, entry for Enalapril in the form Tablet containing enalapril maleate 5 mg

omit from the column headed "Brand": **Enalapril generichealth**

[412] Schedule 5, after entry for Estradiol

insert:

Estradiol	GRP-28649	Transdermal patches 585 micrograms, 8	Transdermal	Estradiol Transdermal System (Sandoz, USA) Estradot 37.5
Estradiol	GRP-28651	Transdermal patches 1.17 mg, 8	Transdermal	Estradiol Transdermal System (Sandoz, USA) Estradot 75

Estradiol	GRP-28652	Transdermal patches 1.56 mg, 8	Transdermal	Estradiol Transdermal System (Sandoz, USA) Estradot 100

[413] Schedule 5, entry for Fluvoxamine

substitute:

Fluvoxamine	GRP-19862	Tablet containing fluvoxamine maleate 100 mg	Oral	APO-Fluvoxamine Faverin 100 Luvox Movox 100
Fluvoxamine	GRP-19729	Tablet containing fluvoxamine maleate 50 mg	Oral	APO-Fluvoxamine Faverin 50 Luvox Movox 50

[414] Schedule 5, entry for Fosinopril

substitute:

Fosinopril	GRP-19785	Tablet containing fosinopril sodium 10 mg	Oral	APO-Fosinopril Monace 10
Fosinopril	GRP-19769	Tablet containing fosinopril sodium 20 mg	Oral	APO-Fosinopril Monace 20

[415] Schedule 5, entry for Furosemide in the form Tablet 20 mg

insert in alphabetical order in the column headed "Brand": **UREMIDE 20**

[416] Schedule 5, entry for Lamivudine with zidovudine

omit from the column headed "Brand": **Lamivudine 150 mg + Zidovudine 300 mg Alphapharm**

[417] Schedule 5, entry for Lercanidipine

substitute:

Lercanidipine	GRP-19911	Tablet containing lercanidipine hydrochloride 10 mg	Oral	BTC Lercanidipine Lercan Lercanidipine APOTEX Zanidip Zircol 10
Lercanidipine	GRP-19829	Tablet containing lercanidipine hydrochloride 20 mg	Oral	ARX-LERCANIDIPINE BTC Lercanidipine Lercan Lercanidipine APOTEX Zanidip Zircol 20

[418] Schedule 5, entry for Medroxyprogesterone

substitute:

Medroxyprogesterone	GRP-19676	Tablet containing medroxyprogesterone acetate 10 mg	Oral	Provera Ralovera
Medroxyprogesterone	GRP-19872	Tablet containing medroxyprogesterone acetate 5 mg	Oral	Provera Ralovera
Medroxyprogesterone	GRP-28650	Injection containing medroxyprogesterone acetate 150 mg in 1 mL	Injection	Depo-Provera Depo-Ralovera
Medroxyprogesterone	GRP-28650	Injection containing medroxyprogesterone acetate 150 mg in 1 mL pre-filled syringe	Injection	Depo-Provera

[419] Schedule 5, entry for Methotrexate in each of the forms: Tablet 10 mg; and Tablet 2.5 mg

insert in alphabetical order in the column headed "Brand": **ARX-Methotrexate**

[420] Schedule 5, entry for Mycophenolic acid in the form Tablet containing mycophenolate mofetil 500 mg

omit from the column headed "Brand": **Noumed Mycophenolate**

[421] Schedule 5, omit entry for Naltrexone

[422] Schedule 5, entry for Nebivolol in each of the forms: Tablet 1.25 mg (as hydrochloride); and Tablet 10 mg (as hydrochloride)

omit from the column headed "Brand": **Nebivolol Viatris**

[423] Schedule 5, entry for Olanzapine

substitute:

Olanzapine	GRP-15921	Tablet 5 mg	Oral	NOUMED OLANZAPINE Olanzapine APOTEX Olanzapine RBX Olanzapine Sandoz Ozin 5 PRYZEX Zypine Zyprexa
Olanzapine	GRP-15513	Tablet 10 mg	Oral	APO-OLANZAPINE NOUMED OLANZAPINE Olanzapine APOTEX Olanzapine RBX Olanzapine Sandoz Ozin 10 PRYZEX Zypine Zyprexa
Olanzapine	GRP-15723	Tablet 10 mg (orally disintegrating)	Oral	APO-Olanzapine ODT Olanzapine ODT generichealth 10 Olanzapine Sandoz ODT 10 PRYZEX ODT Zypine ODT
Olanzapine	GRP-15723	Wafer 10 mg	Oral	Zyprexa Zydis
Olanzapine	GRP-15953	Tablet 15 mg (orally disintegrating)	Oral	APO-Olanzapine ODT Olanzapine Sandoz ODT 15

				PRYZEX ODT Zypine ODT
Olanzapine	GRP-15953	Wafer 15 mg	Oral	Zyprexa Zydis
Olanzapine	GRP-15492	Tablet 2.5 mg	Oral	NOUMED OLANZAPINE Olanzapine APOTEX Olanzapine RBX Olanzapine Sandoz Ozin 2.5 PRYZEX Zypine Zyprexa
Olanzapine	GRP-15643	Tablet 20 mg (orally disintegrating)	Oral	APO-Olanzapine ODT Olanzapine Sandoz ODT 20 PRYZEX ODT Zypine ODT
Olanzapine	GRP-15643	Wafer 20 mg	Oral	Zyprexa Zydis
Olanzapine	GRP-15797	Tablet 5 mg (orally disintegrating)	Oral	APO-Olanzapine ODT Olanzapine Sandoz ODT 5 PRYZEX ODT Zypine ODT
Olanzapine	GRP-15797	Wafer 5 mg	Oral	Zyprexa Zydis
Olanzapine	GRP-15884	Tablet 7.5 mg	Oral	APO-OLANZAPINE NOUMED OLANZAPINE Olanzapine APOTEX Olanzapine RBX Olanzapine Sandoz Ozin 7.5 PRYZEX Zypine

				Zyprexa

[424] **Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 12.5 mg**

omit from the column headed "Schedule Equivalent Group": **GRP- 23700** *substitute:* **GRP-23700**

[425] **Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg**

omit from the column headed "Schedule Equivalent Group": **GRP- 23703** *substitute:* **GRP-23703**

[426] **Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg**

insert in alphabetical order in the column headed "Brand": **Ondansetron ODT Viatris**

[427] **Schedule 5, entry for Ondansetron in each of the forms: Tablet 4 mg (as hydrochloride dihydrate); and Tablet 8 mg (as hydrochloride dihydrate)**

insert in alphabetical order in the column headed "Brand": **Ondansetron Tablets Viatris**

[428] **Schedule 5, entry for Perindopril in each of the forms: Tablet containing perindopril arginine 10 mg; Tablet containing perindopril arginine 2.5 mg; and Tablet containing perindopril arginine 5 mg**

insert in alphabetical order in the column headed "Brand": **Perindopril Arginine Sandoz**

[429] **Schedule 5, entry for Pioglitazone in each of the forms: Tablet 30 mg (as hydrochloride); and Tablet 45 mg (as hydrochloride)**

(a) *omit from the column headed "Brand":* **NOUMED PIOGLITAZONE**

(b) *omit from the column headed "Brand":* **Pioglitazone Sandoz**

[430] **Schedule 5, entry for Plerixafor**

insert in alphabetical order in the column headed "Brand": **PLERIXAFOR EUGIA**

[431] **Schedule 5, entry for Quetiapine in each of the forms: Tablet (modified release) 150 mg (as fumarate); Tablet (modified release) 200 mg (as fumarate); Tablet (modified release) 300 mg (as fumarate); Tablet (modified release) 400 mg (as fumarate); and Tablet (modified release) 50 mg (as fumarate)**

insert in alphabetical order in the column headed "Brand": **Quetiapine Sandoz XR**

[432] **Schedule 5, entry for Ramipril in the form Tablet 2.5 mg**

insert in alphabetical order in the column headed "Brand": **Ramipril Viatris**

[433] **Schedule 5, entry for Rosuvastatin in the form Tablet 10 mg (as calcium)**

(a) *omit from the column headed "Schedule Equivalent Group":* **GRP-19551** *substitute:* **GRP-19558**

(b) *insert in alphabetical order in the column headed "Brand":* **APO-Rosuvastatin**

(c) *omit from the column headed "Brand":* **Noumed Rosuvastatin**

[434] **Schedule 5, entry for Rosuvastatin in the form Tablet 20 mg (as calcium)**

(a) *omit from the column headed "Schedule Equivalent Group":* **GRP-19553** *substitute:* **GRP-19557**

(b) *omit from the column headed "Brand":* **Noumed Rosuvastatin**

[435] **Schedule 5, entry for Rosuvastatin in the form Tablet 40 mg (as calcium)**

(a) *omit from the column headed "Schedule Equivalent Group":* **GRP-19550** *substitute:* **GRP-19562**

(b) *omit from the column headed "Brand":* **Noumed Rosuvastatin**

[436] **Schedule 5, entry for Rosuvastatin in the form Tablet 5 mg (as calcium)**

(a) *omit from the column headed "Schedule Equivalent Group":* **GRP-19552** *substitute:* **GRP-19569**

(b) *omit from the column headed "Brand":* **Noumed Rosuvastatin**

[437] **Schedule 5, entry for Sitagliptin in the form Tablet 100 mg**

omit from the column headed "Schedule Equivalent Group": **GRP-26496** *substitute:* **GRP-26498**

[438] **Schedule 5, entry for Sitagliptin in the form Tablet 25 mg**

omit from the column headed "Schedule Equivalent Group": **GRP-26495** *substitute:* **GRP-26497**

[439] **Schedule 5, entry for Sitagliptin with metformin in the form Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride**

omit from the column headed "Schedule Equivalent Group": **GRP-26455** *substitute:* **GRP-26459**

[440] **Schedule 5, entry for Sitagliptin with metformin in the form Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride**

omit from the column headed "Schedule Equivalent Group": **GRP-26448** *substitute:* **GRP-26454**

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

insert in alphabetical order in the column headed "Brand": **IMIGRAN MIGRAINE**

[442] Schedule 5, after entry for Teriparatide in the form Injection 250 micrograms per mL, 2.4 mL in multi-dose pre-filled pen

insert:

Testosterone	GRP-28648	I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL	Injection	Reandron 1000 Testosterone ADVZ 1000

[443] Schedule 5, entry for Valaciclovir in the form Tablet 500 mg (as hydrochloride)

(a) *omit from the column headed "Schedule Equivalent Group":* **GRP-19634** *substitute:* **GRP-19726**

(b) *omit from the column headed "Brand":* **NOUMED VALACICLOVIR**