PB 113 of 2026

National Health (Listing of Pharmaceutical Benefits) Amendment (October Update) Instrument 2026

National Health Act 1953

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

Dated 30 September 2026

MIKE POPE
Assistant Secretary
PBS Listing, Pricing and Policy Branch
Technology Assessment and Access Division

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1. Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (October Update) Instrument 2026*.

(2) This Instrument may also be cited as PB 113 of 2026.

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 October 2026	1 October 2026

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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Schedule 1—Amendments

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

[1] Schedule 1, Part 1, entry for Abemaciclib in the form Tablet 50 mg

(a) omit from the column headed "Circumstances": C17907

(b) insert in numerical order in the column headed "Circumstances": C19282

[2] Schedule 1, Part 1, entry for Abemaciclib in the form Tablet 100 mg

(a) omit from the column headed "Circumstances": C17907

(b) insert in numerical order in the column headed "Circumstances": C19282

[3] Schedule 1, Part 1, entry for Abemaciclib in the form Tablet 150 mg

(a) omit from the column headed "Circumstances": C17907

(b) insert in numerical order in the column headed "Circumstances": C19282

[4] Schedule 1, Part 1, after entry for Adalimumab in the form Injection 20 mg in 0.2 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 6]*

insert:

Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C15473 C18989	P15473 P18989	2	0	2	
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C12120 C17707 C17713 C17717 C17719 C17733 C17734	See Note 3	See Note 3	See Note 3	2	C(100)
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C16982 C17031 C17032 C17077 C17715 C17731 C18966 C18967 C18968	P16982 P17031 P17032 P17077 P17715 P17731 P18966 P18967 P18968	2	3	2	
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C17005 C17042 C17043 C17044 C17045 C17046	P17005 P17042 P17043 P17044 P17045 P17046	2	4	2	

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Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C15445 C15446 C16991 C16993 C16999 C17002 C17003 C17030 C17065 C17730 C17736 C18991	P15445 P15446 P16991 P16993 P16999 P17002 P17003 P17030 P17065 P17730 P17736 P18991	2	5	2
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe	Injection	Yuflyma	EW	MP	C15474 C15489	P15474 P15489	2	6	2

[5] Schedule 1, Part 1, entries for Allopurinol in the form Tablet 300 mg

omit:

Allopurinol	Tablet 300 mg	Oral	NOUMED ALLOPURINOL	VO	MP NP			60	2	60
Allopurinol	Tablet 300 mg	Oral	NOUMED ALLOPURINOL	VO	MP NP		P14238	120	2	60

[6] Schedule 1, Part 1, after entry for Apixaban in the form Tablet 2.5 mg *[Brand: Apixaban-APX; Maximum Quantity: 120; Number of Repeats: 5]*

insert:

Apixaban	Tablet 2.5 mg	Oral	Apixaban Dr.Reddy's	RI	MP NP	C4359 C4381	P4359 P4381	20	0	20
Apixaban	Tablet 2.5 mg	Oral	Apixaban Dr.Reddy's	RI	MP NP	C4382 C4409	P4382 P4409	30	0	30
Apixaban	Tablet 2.5 mg	Oral	Apixaban Dr.Reddy's	RI	MP NP	C4402	P4402	60	0	60
Apixaban	Tablet 2.5 mg	Oral	Apixaban Dr.Reddy's	RI	MP NP	C4132 C4269	P4132 P4269	60	5	60
Apixaban	Tablet 2.5 mg	Oral	Apixaban Dr.Reddy's	RI	MP NP	C14300 C14301	P14300 P14301	120	5	60

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

insert:

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Apixaban	Tablet 2.5 mg	Oral	Apixaban Viatris	AF	MP NP	C4402	P4402	60	0	60
Apixaban	Tablet 2.5 mg	Oral	Apixaban Viatris	AF	MP NP	C4132 C4269	P4132 P4269	60	5	60
Apixaban	Tablet 2.5 mg	Oral	Apixaban Viatris	AF	MP NP	C14300 C14301	P14300 P14301	120	5	60

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

insert:

Apixaban	Tablet 2.5 mg	Oral	MSN-APIXABAN	VM	MP NP	C4359 C4381	P4359 P4381	20	0	20
Apixaban	Tablet 2.5 mg	Oral	MSN-APIXABAN	VM	MP NP	C4382 C4409	P4382 P4409	30	0	30
Apixaban	Tablet 2.5 mg	Oral	MSN-APIXABAN	VM	MP NP	C4402	P4402	60	0	60
Apixaban	Tablet 2.5 mg	Oral	MSN-APIXABAN	VM	MP NP	C4132 C4269	P4132 P4269	60	5	60
Apixaban	Tablet 2.5 mg	Oral	MSN-APIXABAN	VM	MP NP	C14300 C14301	P14300 P14301	120	5	60

[9] **Schedule 1, Part 1, after entry for Apixaban in the form Tablet 5 mg *[Brand: Apixaban-APX; Maximum Quantity: 120; Number of Repeats: 5]***

insert:

Apixaban	Tablet 5 mg	Oral	Apixaban Dr.Reddy's	RI	MP NP	C4269 C18513 C18522	P4269 P18513 P18522	60	5	60
Apixaban	Tablet 5 mg	Oral	Apixaban Dr.Reddy's	RI	MP NP	C14301 C18525 C18527	P14301 P18525 P18527	120	5	60

[10] **Schedule 1, Part 1, after entry for Apixaban in the form Tablet 5 mg *[Brand: Apixaban Sandoz; Maximum Quantity: 120; Number of Repeats: 5]***

insert:

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Apixaban	Tablet 5 mg	Oral	Apixaban Viatris	AF	MP NP	C4269 C18513 C18522	P4269 P18513 P18522	60	5	60	
Apixaban	Tablet 5 mg	Oral	Apixaban Viatris	AF	MP NP	C14301 C18525 C18527	P14301 P18525 P18527	120	5	60	

[11] Schedule 1, Part 1, after entry for Apixaban in the form Tablet 5 mg *[Brand: Eliquis; Maximum Quantity: 120; Number of Repeats: 5]*

insert:

Apixaban	Tablet 5 mg	Oral	MSN-APIXABAN	VM	MP NP	C4269 C18513 C18522	P4269 P18513 P18522	60	5	60	
Apixaban	Tablet 5 mg	Oral	MSN-APIXABAN	VM	MP NP	C14301 C18525 C18527	P14301 P18525 P18527	120	5	60	

[12] Schedule 1, Part 1, entries for Apomorphine

substitute:

Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 50 mg in 5 mL	Injection	Movapo	TD	MP NP	C10844	P10844	180	5	5	
Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 50 mg in 5 mL	Injection	Movapo	TD	MP	C11385 C11445	P11385 P11445	180	5	5	C(100)
Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 50 mg in 5 mL	Injection	Movapo	TD	MP NP	C15542	P15542	360	5	5	
Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL	Injection	Apomine Solution for Infusion	IT	MP NP	C10844	P10844	90	5	5	
Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL	Injection	Apomine Solution for Infusion	IT	MP	C10830 C10863	P10830 P10863	90	5	5	C(100)
Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 100 mg in	Injection	Apomine Solution for Infusion	IT	MP NP	C15542	P15542	180	5	5	

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	20 mL										
Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL	Injection	MOVAPO POD	TD	MP NP	C10844	P10844	90	5	5	
Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL	Injection	MOVAPO POD	TD	MP	C10830 C10863	P10830 P10863	90	5	5	C(100)
Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL	Injection	MOVAPO POD	TD	MP NP	C15542	P15542	180	5	5	
Apomorphine	Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe	Injection	Movapo PFS	TD	MP NP	C10844	P10844	180	5	5	
Apomorphine	Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe	Injection	Movapo PFS	TD	MP	C11385 C11445	P11385 P11445	180	5	5	C(100)
Apomorphine	Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe	Injection	Movapo PFS	TD	MP NP	C15542	P15542	360	5	5	
Apomorphine	Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen	Injection	Apomine Intermittent	IT	MP NP	C10844	P10844	100	5	5	
Apomorphine	Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen	Injection	Apomine Intermittent	IT	MP	C10830 C10863	P10830 P10863	100	5	5	C(100)

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Apomorphine	Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen	Injection	Apomine Intermittent	IT	MP NP	C15542	P15542	200	5	5	
Apomorphine	Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen	Injection	Movapo Pen	TD	MP NP	C10844	P10844	100	5	5	
Apomorphine	Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen	Injection	Movapo Pen	TD	MP	C10830 C10863	P10830 P10863	100	5	5	C(100)
Apomorphine	Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen	Injection	Movapo Pen	TD	MP NP	C15542	P15542	200	5	5	

[13] Schedule 1, Part 1, entry for Asciminib in the form Tablet 20 mg *[Authorised Prescriber: MP NP]*

omit from the column headed "Circumstances": C19201 *substitute:* C19234

[14] Schedule 1, Part 1, entry for Asciminib in the form Tablet 20 mg *[Authorised Prescriber: MP]*

omit from the column headed "Circumstances": C13950 *substitute:* C19260

[15] Schedule 1, Part 1, entry for Asciminib in the form Tablet 40 mg *[Authorised Prescriber: MP NP; Maximum Quantity: 60; Number of Repeats: 5]*

(a) omit from the column headed "Circumstances": C19201 *substitute:* C19234

(b) omit from the column headed "Purposes": P19201 *substitute:* P19234

[16] Schedule 1, Part 1, entry for Asciminib in the form Tablet 40 mg *[Authorised Prescriber: MP]*

(a) omit from the column headed "Circumstances": C13950 *substitute:* C19260

(b) omit from the column headed "Purposes": P13950 *substitute:* P19260

[17] Schedule 1, Part 1, entry for Asciminib in the form Tablet 40 mg *[Authorised Prescriber: MP NP; Maximum Quantity: 300; Number of Repeats: 5]*

(a) omit from the column headed "Circumstances": C19202

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(b) insert in numerical order in the column headed "Circumstances": C19277

(c) omit from the column headed "Purposes": P19202

(d) insert in numerical order in the column headed "Purposes": P19277

[18] Schedule 1, Part 1, after entry for Bivalirudin *[Brand: BIVALIRUDIN MEDSURGE]*

insert:

Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U.	Injection	Bleomycin Accord	OC	MP	C6224 C6275		See Note 3	See Note 3	1	D(100)

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

(a) insert in the column headed "Pack Quantity": 1

(b) omit from the column headed "Determined Quantity": 1

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

substitute:

Ceftriaxone	Powder for injection 500 mg (as sodium)	Injection	Ceftriaxone-AFT	AE	MP MW NP	C5855	P5855	1	0	1	
Ceftriaxone	Powder for injection 500 mg (as sodium)	Injection	Ceftriaxone-AFT	AE	MP MW NP	C15964	P15964	5	0	1	
Ceftriaxone	Powder for injection 500 mg (as sodium)	Injection	Ceftriaxone-AFT	AE	MP NP	C16029 C16030	P16029 P16030	5	0	1	
Ceftriaxone	Powder for injection 1 g (as sodium)	Injection	Ceftriaxone Viatris	AL	MP MW NP	C15964		5	0	10	
Ceftriaxone	Powder for injection 1 g (as sodium)	Injection	Ceftriaxone Viatris	AL	MP NP	C16029 C16030		5	0	10	
Ceftriaxone	Powder for injection 2 g (as sodium)	Injection	Ceftriaxone Viatris	AL	MP MW NP	C15964		5	0	5	

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Ceftriaxone	Powder for injection 2 g (as sodium)	Injection	Ceftriaxone Viatris	AL	MP NP	C16029 C16030	5	0	5
Ceftriaxone	Powder for injection 2 g (as sodium)	Injection	Ceftriaxone Viatris	AL	MP MW NP	C15964	5	0	10
Ceftriaxone	Powder for injection 2 g (as sodium)	Injection	Ceftriaxone Viatris	AL	MP NP	C16029 C16030	5	0	10

[21] Schedule 1, Part 1, entries for Cefuroxime

substitute:

Cefuroxime	Tablet 250 mg (as axetil)	Oral	ARX-Cefuroxime	XT	PDP		14	0	14
Cefuroxime	Tablet 250 mg (as axetil)	Oral	ARX-Cefuroxime	XT	MP NP		14	1	14
Cefuroxime	Tablet 250 mg (as axetil)	Oral	ARX-Cefuroxime	XT	PDP		20	0	20
Cefuroxime	Tablet 250 mg (as axetil)	Oral	ARX-Cefuroxime	XT	MP NP		20	1	20
Cefuroxime	Tablet 250 mg (as axetil)	Oral	Pharmacor Cefuroxime	CR	PDP		14	0	14
Cefuroxime	Tablet 250 mg (as axetil)	Oral	Pharmacor Cefuroxime	CR	MP NP		14	1	14
Cefuroxime	Tablet 250 mg (as axetil)	Oral	Pharmacor Cefuroxime	CR	PDP		20	0	20
Cefuroxime	Tablet 250 mg (as axetil)	Oral	Pharmacor Cefuroxime	CR	MP NP		20	1	20
Cefuroxime	Tablet 250 mg (as axetil)	Oral	Zinnat	AS	PDP		20	0	20
Cefuroxime	Tablet 250 mg (as axetil)	Oral	Zinnat	AS	MP NP		20	1	20

[22] Schedule 1, Part 1, entry for Ciclosporin in the form Eye drops 900 micrograms per mL, single dose units 0.25 mL, 60

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

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[23] Schedule 1, Part 1, entry for Ciclosporin in the form Eye drops 1 mg per mL, single dose units 0.3 mL, 30

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

[24] Schedule 1, Part 1, after entry for Ciclosporin in the form Eye drops 1 mg per mL, single dose units 0.3 mL, 30

insert:

Ciclosporin	Eye drops 1 mg per mL, 2 mL	Application to the eye	Vevye	AE	AO MP	C14026 C14032	1	5	1

[25] Schedule 1, Part 1, entries for Corifollitropin alfa

omit from the column headed "Responsible Person" (all instances): OQ *substitute (all instances):* AF

[26] Schedule 1, Part 1, entries for Dasatinib

substitute:

Dasatinib	Tablet 20 mg	Oral	Dasatinib ARX	XT	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib ARX	XT	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib ARX	XT	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib Dr.Reddy's	RI	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib Dr.Reddy's	RI	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib Dr.Reddy's	RI	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib Sandoz	SZ	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib Sandoz	SZ	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib Sandoz	SZ	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib SUN	RA	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60

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Dasatinib	Tablet 20 mg	Oral	Dasatinib SUN	RA	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib SUN	RA	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 20 mg	Oral	DASATINIB-TEVA	TB	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 20 mg	Oral	DASATINIB-TEVA	TB	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 20 mg	Oral	DASATINIB-TEVA	TB	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib Viatris	AL	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib Viatris	AL	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 20 mg	Oral	Dasatinib Viatris	AL	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 20 mg	Oral	Sprycel	BQ	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 20 mg	Oral	Sprycel	BQ	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 20 mg	Oral	Sprycel	BQ	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib ARX	XT	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib ARX	XT	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib ARX	XT	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib Dr.Reddy's	RI	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib Dr.Reddy's	RI	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib Dr.Reddy's	RI	MP	C19223	P19223	60	5	60

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Dasatinib	Tablet 50 mg	Oral	Dasatinib Sandoz	SZ	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib Sandoz	SZ	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib Sandoz	SZ	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib SUN	RA	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib SUN	RA	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib SUN	RA	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 50 mg	Oral	DASATINIB-TEVA	TB	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 50 mg	Oral	DASATINIB-TEVA	TB	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 50 mg	Oral	DASATINIB-TEVA	TB	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib Viatris	AL	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib Viatris	AL	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 50 mg	Oral	Dasatinib Viatris	AL	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 50 mg	Oral	Sprycel	BQ	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 50 mg	Oral	Sprycel	BQ	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 50 mg	Oral	Sprycel	BQ	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib ARX	XT	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib ARX	XT	MP NP	C19225	P19225	60	5	60

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Dasatinib	Tablet 70 mg	Oral	Dasatinib ARX	XT	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib Dr.Reddy's	RI	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib Dr.Reddy's	RI	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib Dr.Reddy's	RI	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib Sandoz	SZ	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib Sandoz	SZ	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib Sandoz	SZ	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib SUN	RA	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib SUN	RA	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib SUN	RA	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 70 mg	Oral	DASATINIB-TEVA	TB	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 70 mg	Oral	DASATINIB-TEVA	TB	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 70 mg	Oral	DASATINIB-TEVA	TB	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib Viatris	AL	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib Viatris	AL	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 70 mg	Oral	Dasatinib Viatris	AL	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 70 mg	Oral	Sprycel	BQ	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	60	2	60

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Dasatinib	Tablet 70 mg	Oral	Sprycel	BQ	MP NP	C19225	P19225	60	5	60
Dasatinib	Tablet 70 mg	Oral	Sprycel	BQ	MP	C19223	P19223	60	5	60
Dasatinib	Tablet 100 mg	Oral	Dasatinib ARX	XT	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	30	2	30
Dasatinib	Tablet 100 mg	Oral	Dasatinib ARX	XT	MP NP	C19225	P19225	30	5	30
Dasatinib	Tablet 100 mg	Oral	Dasatinib ARX	XT	MP	C19223	P19223	30	5	30
Dasatinib	Tablet 100 mg	Oral	Dasatinib Dr.Reddy's	RI	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	30	2	30
Dasatinib	Tablet 100 mg	Oral	Dasatinib Dr.Reddy's	RI	MP NP	C19225	P19225	30	5	30
Dasatinib	Tablet 100 mg	Oral	Dasatinib Dr.Reddy's	RI	MP	C19223	P19223	30	5	30
Dasatinib	Tablet 100 mg	Oral	Dasatinib Sandoz	SZ	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	30	2	30
Dasatinib	Tablet 100 mg	Oral	Dasatinib Sandoz	SZ	MP NP	C19225	P19225	30	5	30
Dasatinib	Tablet 100 mg	Oral	Dasatinib Sandoz	SZ	MP	C19223	P19223	30	5	30
Dasatinib	Tablet 100 mg	Oral	Dasatinib SUN	RA	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	30	2	30
Dasatinib	Tablet 100 mg	Oral	Dasatinib SUN	RA	MP NP	C19225	P19225	30	5	30
Dasatinib	Tablet 100 mg	Oral	Dasatinib SUN	RA	MP	C19223	P19223	30	5	30
Dasatinib	Tablet 100 mg	Oral	DASATINIB-TEVA	TB	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	30	2	30
Dasatinib	Tablet 100 mg	Oral	DASATINIB-TEVA	TB	MP NP	C19225	P19225	30	5	30
Dasatinib	Tablet 100 mg	Oral	DASATINIB-TEVA	TB	MP	C19223	P19223	30	5	30

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Dasatinib	Tablet 100 mg	Oral	Dasatinib Viatris	AL	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	30	2	30
Dasatinib	Tablet 100 mg	Oral	Dasatinib Viatris	AL	MP NP	C19225	P19225	30	5	30
Dasatinib	Tablet 100 mg	Oral	Dasatinib Viatris	AL	MP	C19223	P19223	30	5	30
Dasatinib	Tablet 100 mg	Oral	Sprycel	BQ	MP NP	C17817 C17821 C17879 C17984	P17817 P17821 P17879 P17984	30	2	30
Dasatinib	Tablet 100 mg	Oral	Sprycel	BQ	MP NP	C19225	P19225	30	5	30
Dasatinib	Tablet 100 mg	Oral	Sprycel	BQ	MP	C19223	P19223	30	5	30

[27] Schedule 1, Part 1, entry for Dupilumab in the form Injection 200 mg in 1.14 mL single dose pre-filled pen *[Maximum Quantity: See Note 3]*

(a) omit from the column headed "Circumstances": C17073 C17113

(b) insert in numerical order in the column headed "Circumstances": C19236

[28] Schedule 1, Part 1, entry for Dupilumab in the form Injection 200 mg in 1.14 mL single dose pre-filled syringe *[Maximum Quantity: See Note 3]*

(a) omit from the column headed "Circumstances": C17073 C17113

(b) insert in numerical order in the column headed "Circumstances": C19236

[29] Schedule 1, Part 1, entry for Dupilumab in the form Injection 300 mg in 2 mL single dose pre-filled pen *[Maximum Quantity: See Note 3]*

(a) omit from the column headed "Circumstances": C17073 C17113

(b) insert in numerical order in the column headed "Circumstances": C19236

[30] Schedule 1, Part 1, entry for Dupilumab in the form Injection 300 mg in 2 mL single dose pre-filled syringe *[Maximum Quantity: See Note 3]*

(a) omit from the column headed "Circumstances": C17073 C17113

(b) insert in numerical order in the column headed "Circumstances": C19236

[31] Schedule 1, Part 1, entry for Edaravone *[Maximum Quantity: 20; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C16479 *substitute:* C19267

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(b) *omit from the column headed "Purposes":* P16479 *substitute:* P19267

[32] Schedule 1, Part 1, entry for Edaravone *[Maximum Quantity: 28; Number of Repeats: 0]*

(a) *omit from the column headed "Circumstances":* C18480 *substitute:* C19252

(b) *omit from the column headed "Purposes":* P18480 *substitute:* P19252

[33] Schedule 1, Part 1, entries for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4

omit:

Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Nepexto	GQ	MP	C12120 C17706 C17707 C17713 C17724 C17725	See Note 3	See Note 3	See Note 3	1	C(100)
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Nepexto	GQ	MP	C14508 C14509	P14508 P14509	1	1	1	
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Nepexto	GQ	MP	C9064 C9386 C12261 C14488 C14513 C14553 C14554 C14576 C14577 C14581 C14582 C14603 C14670 C14671 C14673 C14703 C16709 C16710 C16713 C16716 C16717 C16727 C16728 C16737 C16743 C16747 C16761 C16763 C16764 C16773 C16777 C16779 C16785 C16788 C17001 C17069 C17355	P9064 P9386 P12261 P14488 P14513 P14553 P14554 P14576 P14577 P14581 P14582 P14603 P14670 P14671 P14673 P14703 P16709 P16710 P16713 P16716 P16717 P16727 P16728 P16737 P16743 P16747 P16761 P16763 P16764 P16773 P16777 P16779 P16785 P16788 P17001 P17069 P17355	1	3	1	
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection	Nepexto	GQ	MP	C9081 C12123 C14499 C14507 C14629 C14683 C14701 C14715 C16718 C16720 C16725 C16750	P9081 P12123 P14499 P14507 P14629 P14683 P14701 P14715 P16718 P16720 P16725 P16750	1	5	1	

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						C16754 C16765 C16766 C16772 C16775 C16778 C16787 C16789 C16792 C16795 C17326 C17374		P16754 P16765 P16766 P16772 P16775 P16778 P16787 P16789 P16792 P16795 P17326 P17374		

[34] **Schedule 1, Part 1, entry for Follitropin beta in the form Solution for injection 300 I.U. in 0.36 mL multi-dose cartridge *[Maximum Quantity: 2; Number of Repeats: 0]***

omit from the column headed "Responsible Person": OQ *substitute:* AF

[35] **Schedule 1, Part 1, entry for Follitropin beta in the form Solution for injection 300 I.U. in 0.36 mL multi-dose cartridge *[Maximum Quantity: 3; Number of Repeats: 5]***

omit from the column headed "Responsible Person": OQ *substitute:* AF

[36] **Schedule 1, Part 1, entry for Follitropin beta in the form Solution for injection 600 I.U. in 0.72 mL multi-dose cartridge *[Maximum Quantity: 2; Number of Repeats: 5]***

omit from the column headed "Responsible Person": OQ *substitute:* AF

[37] **Schedule 1, Part 1, entry for Follitropin beta in the form Solution for injection 600 I.U. in 0.72 mL multi-dose cartridge *[Maximum Quantity: 4; Number of Repeats: 0]***

omit from the column headed "Responsible Person": OQ *substitute:* AF

[38] **Schedule 1, Part 1, entry for Follitropin beta in the form Solution for injection 900 I.U. in 1.08 mL multi-dose cartridge *[Maximum Quantity: 2; Number of Repeats: 5]***

omit from the column headed "Responsible Person": OQ *substitute:* AF

[39] **Schedule 1, Part 1, entry for Follitropin beta in the form Solution for injection 900 I.U. in 1.08 mL multi-dose cartridge *[Maximum Quantity: 5; Number of Repeats: 0]***

omit from the column headed "Responsible Person": OQ *substitute:* AF

[40] **Schedule 1, Part 1, after entry for Gabapentin in the form Tablet 600 mg *[Brand: Pharmacor Gabapentin 600]***

insert:

Gabapentin	Tablet 800 mg	Oral	APX-GABAPENTIN	XT	MP NP	C17445	100	5	100	

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[41] Schedule 1, Part 1, entries for Gabapentin in the form Tablet 800 mg

omit:

Gabapentin	Tablet 800 mg	Oral	Gabapentin APOTEX	TY	MP NP	C17445	100	5	100

[42] Schedule 1, Part 1, after entry for Glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine in the form Sachets containing oral powder 35 g, 30 (PKU Sphere20)

insert:

Glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine	Sachets containing oral powder 40 g, pack of 30 (PKU GMPro Delight)	Oral	PKU GMPro Delight	SB	MP NP	C4295	4	5	1

[43] Schedule 1, Part 1, after entry for Griseofulvin in the form Tablet 500 mg

insert:

Guanfacine	Tablet 1 mg (as hydrochloride)	Oral	Guanfacine MHC	XT	MP NP	C8544 C8585 C9031 C9034	28	5	28

[44] Schedule 1, Part 1, after entry for Guanfacine in the form Tablet 1 mg (as hydrochloride) *[Brand: Intuniv]*

insert:

Guanfacine	Tablet 2 mg (as hydrochloride)	Oral	Guanfacine MHC	XT	MP NP	C8544 C8585 C9031 C9034	28	5	28

[45] Schedule 1, Part 1, after entry for Guanfacine in the form Tablet 2 mg (as hydrochloride) *[Brand: Intuniv]*

insert:

Guanfacine	Tablet 3 mg (as hydrochloride)	Oral	Guanfacine MHC	XT	MP NP	C8544 C8585 C9031 C9034	28	5	28

[46] Schedule 1, Part 1, after entry for Guanfacine in the form Tablet 3 mg (as hydrochloride) *[Brand: Intuniv]*

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insert:

Guanfacine	Tablet 4 mg (as hydrochloride)	Oral	Guanfacine MHC	XT	MP NP	C8544 C8585 C9031 C9034		28	5	28

[47] Schedule 1, Part 1, entries for Imatinib

substitute:

Imatinib	Capsule 100 mg (as mesilate)	Oral	ARX-IMATINIB	XT	MP NP	C17826 C17886	P17826 P17886	60	2	60
Imatinib	Capsule 100 mg (as mesilate)	Oral	ARX-IMATINIB	XT	MP	C9319 C16238	P9319 P16238	60	2	60
Imatinib	Capsule 100 mg (as mesilate)	Oral	ARX-IMATINIB	XT	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	60	5	60
Imatinib	Capsule 100 mg (as mesilate)	Oral	ARX-IMATINIB	XT	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	60	5	60
Imatinib	Capsule 100 mg (as mesilate)	Oral	IMATINIB-DRLA	RZ	MP NP	C17826 C17886	P17826 P17886	60	2	60
Imatinib	Capsule 100 mg (as mesilate)	Oral	IMATINIB-DRLA	RZ	MP	C9319 C16238	P9319 P16238	60	2	60
Imatinib	Capsule 100 mg (as mesilate)	Oral	IMATINIB-DRLA	RZ	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	60	5	60
Imatinib	Capsule 100 mg (as mesilate)	Oral	IMATINIB-DRLA	RZ	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	60	5	60
Imatinib	Capsule 400 mg (as mesilate)	Oral	ARX-IMATINIB	XT	MP NP	C17826 C17886	P17826 P17886	30	2	30
Imatinib	Capsule 400 mg (as mesilate)	Oral	ARX-IMATINIB	XT	MP	C9319 C16238	P9319 P16238	30	2	30
Imatinib	Capsule 400 mg (as mesilate)	Oral	ARX-IMATINIB	XT	MP NP	C17884 C17885 C17887 C17890	P17884 P17885 P17887 P17890	30	5	30

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						C17960 C19225	P17960 P19225			
Imatinib	Capsule 400 mg (as mesilate)	Oral	ARX-IMATINIB	XT	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	30	5	30
Imatinib	Capsule 400 mg (as mesilate)	Oral	IMATINIB-DRLA	RZ	MP NP	C17826 C17886	P17826 P17886	30	2	30
Imatinib	Capsule 400 mg (as mesilate)	Oral	IMATINIB-DRLA	RZ	MP	C9319 C16238	P9319 P16238	30	2	30
Imatinib	Capsule 400 mg (as mesilate)	Oral	IMATINIB-DRLA	RZ	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	30	5	30
Imatinib	Capsule 400 mg (as mesilate)	Oral	IMATINIB-DRLA	RZ	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	30	5	30
Imatinib	Capsule 400 mg (as mesilate)	Oral	Imatinib GH	GQ	MP NP	C17826 C17886	P17826 P17886	30	2	30
Imatinib	Capsule 400 mg (as mesilate)	Oral	Imatinib GH	GQ	MP	C9319 C16238	P9319 P16238	30	2	30
Imatinib	Capsule 400 mg (as mesilate)	Oral	Imatinib GH	GQ	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	30	5	30
Imatinib	Capsule 400 mg (as mesilate)	Oral	Imatinib GH	GQ	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	30	5	30
Imatinib	Tablet 100 mg (as mesilate)	Oral	Gilmat	CR	MP NP	C17826 C17886	P17826 P17886	60	2	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Gilmat	CR	MP	C9319 C16238	P9319 P16238	60	2	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Gilmat	CR	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	60	5	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Gilmat	CR	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	60	5	60

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Imatinib	Tablet 100 mg (as mesilate)	Oral	Glivec	NV	MP NP	C17826 C17886	P17826 P17886	60	2	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Glivec	NV	MP	C9319 C16238	P9319 P16238	60	2	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Glivec	NV	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	60	5	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Glivec	NV	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	60	5	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Imanib	AF	MP NP	C17826 C17886	P17826 P17886	60	2	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Imanib	AF	MP	C9319 C16238	P9319 P16238	60	2	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Imanib	AF	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	60	5	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Imanib	AF	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	60	5	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	IMATINIB RBX	RA	MP NP	C17826 C17886	P17826 P17886	60	2	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	IMATINIB RBX	RA	MP	C9319 C16238	P9319 P16238	60	2	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	IMATINIB RBX	RA	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	60	5	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	IMATINIB RBX	RA	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	60	5	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Imatinib Sandoz	SZ	MP NP	C17826 C17886	P17826 P17886	60	2	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Imatinib Sandoz	SZ	MP	C9319 C16238	P9319 P16238	60	2	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Imatinib Sandoz	SZ	MP	C17884 C17885 C17887 C17890	P17884 P17885 P17887 P17890	60	5	60

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					NP	C17960 C19225	P17960 P19225			
Imatinib	Tablet 100 mg (as mesilate)	Oral	Imatinib Sandoz	SZ	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	60	5	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Imatinib-Teva	TB	MP NP	C17826 C17886	P17826 P17886	60	2	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Imatinib-Teva	TB	MP	C9319 C16238	P9319 P16238	60	2	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Imatinib-Teva	TB	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	60	5	60
Imatinib	Tablet 100 mg (as mesilate)	Oral	Imatinib-Teva	TB	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	60	5	60
Imatinib	Tablet 400 mg (as mesilate)	Oral	Gilmat	CR	MP NP	C17826 C17886	P17826 P17886	30	2	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Gilmat	CR	MP	C9319 C16238	P9319 P16238	30	2	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Gilmat	CR	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	30	5	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Gilmat	CR	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	30	5	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Glivec	NV	MP NP	C17826 C17886	P17826 P17886	30	2	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Glivec	NV	MP	C9319 C16238	P9319 P16238	30	2	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Glivec	NV	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	30	5	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Glivec	NV	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	30	5	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Imanib	AF	MP	C17826 C17886	P17826 P17886	30	2	30

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					NP					
Imatinib	Tablet 400 mg (as mesilate)	Oral	Imanib	AF	MP	C9319 C16238	P9319 P16238	30	2	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Imanib	AF	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	30	5	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Imanib	AF	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	30	5	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	IMATINIB RBX	RA	MP NP	C17826 C17886	P17826 P17886	30	2	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	IMATINIB RBX	RA	MP	C9319 C16238	P9319 P16238	30	2	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	IMATINIB RBX	RA	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	30	5	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	IMATINIB RBX	RA	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	30	5	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Imatinib Sandoz	SZ	MP NP	C17826 C17886	P17826 P17886	30	2	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Imatinib Sandoz	SZ	MP	C9319 C16238	P9319 P16238	30	2	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Imatinib Sandoz	SZ	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	30	5	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Imatinib Sandoz	SZ	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	30	5	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Imatinib-Teva	TB	MP NP	C17826 C17886	P17826 P17886	30	2	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Imatinib-Teva	TB	MP	C9319 C16238	P9319 P16238	30	2	30
Imatinib	Tablet 400 mg (as mesilate)	Oral	Imatinib-Teva	TB	MP NP	C17884 C17885 C17887 C17890 C17960 C19225	P17884 P17885 P17887 P17890 P17960 P19225	30	5	30

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Imatinib	Tablet 400 mg (as mesilate)	Oral	Imatinib-Teva	TB	MP	C9204 C9238 C9240 C9274 C9276 C19223	P9204 P9238 P9240 P9274 P9276 P19223	30	5	30	
Imatinib	Tablet 600 mg (as mesilate)	Oral	Imatab	JU	MP NP	C17826 C17886	P17826 P17886	30	2	30	
Imatinib	Tablet 600 mg (as mesilate)	Oral	Imatab	JU	MP	C12685 C16238	P12685 P16238	30	2	30	
Imatinib	Tablet 600 mg (as mesilate)	Oral	Imatab	JU	MP NP	C17884 C19225	P17884 P19225	30	5	30	
Imatinib	Tablet 600 mg (as mesilate)	Oral	Imatab	JU	MP	C9240 C19223	P9240 P19223	30	5	30	

[48] Schedule 1, Part 1, entries for Lenalidomide in the form Capsule 5 mg

omit:

Lenalidomide	Capsule 5 mg	Oral	Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
Lenalidomide	Capsule 5 mg	Oral	Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
Lenalidomide	Capsule 5 mg	Oral	Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)

[49] Schedule 1, Part 1, entries for Lenalidomide in the form Capsule 10 mg

omit:

Lenalidomide	Capsule 10 mg	Oral	Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
Lenalidomide	Capsule 10 mg	Oral	Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
Lenalidomide	Capsule 10 mg	Oral	Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)

[50] Schedule 1, Part 1, entries for Lenalidomide in the form Capsule 15 mg

omit:

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Lenalidomide	Capsule 15 mg	Oral	Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
Lenalidomide	Capsule 15 mg	Oral	Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)
Lenalidomide	Capsule 15 mg	Oral	Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	28	D(100)

[51] Schedule 1, Part 1, entries for Lenalidomide in the form Capsule 25 mg

omit:

Lenalidomide	Capsule 25 mg	Oral	Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)
Lenalidomide	Capsule 25 mg	Oral	Lenalidomide Dr.Reddy's	RI	MP	See Note 3	See Note 3	See Note 3	See Note 3	21	D(100)

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

omit:

Levetiracetam	Tablet 500 mg	Oral	Levetiracetam Mylan	AL	MP NP	C17460	P17460	60	5	60
Levetiracetam	Tablet 500 mg	Oral	Levetiracetam Mylan	AL	MP NP	C17543	P17543	120	5	60

[53] Schedule 1, Part 1, entry for Lumasiran *[Maximum Quantity: 5; Number of Repeats: 1]*

(a) omit from the column headed "Circumstances": C17579

(b) omit from the column headed "Purposes": P17579

[54] Schedule 1, Part 1, entry for Modafinil *[Brand: APO-Modafinil]*

(a) omit from the column headed "Circumstances": C10970

(b) insert in numerical order in the column headed "Circumstances": C18333

[55] Schedule 1, Part 1, entry for Modafinil *[Brand: Modafin]*

(a) omit from the column headed "Circumstances": C10970

(b) insert in numerical order in the column headed "Circumstances": C18333

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[56] Schedule 1, Part 1, entry for Modafinil *[Brand: Modafinil GH]*

(a) omit from the column headed "Circumstances": C10970

(b) insert in numerical order in the column headed "Circumstances": C18333

[57] Schedule 1, Part 1, entry for Modafinil *[Brand: Modafinil Sandoz]*

(a) omit from the column headed "Circumstances": C10970

(b) insert in numerical order in the column headed "Circumstances": C18333

[58] Schedule 1, Part 1, entry for Modafinil *[Brand: Modafinil Viatris]*

(a) omit from the column headed "Circumstances": C10970

(b) insert in numerical order in the column headed "Circumstances": C18333

[59] Schedule 1, Part 1, entry for Modafinil *[Brand: MODAFINIL-WGR]*

(a) omit from the column headed "Circumstances": C10970

(b) insert in numerical order in the column headed "Circumstances": C18333

[60] Schedule 1, Part 1, entry for Modafinil *[Brand: Modavigil]*

(a) omit from the column headed "Circumstances": C10970

(b) insert in numerical order in the column headed "Circumstances": C18333

[61] Schedule 1, Part 1, entries for Nilotinib

substitute:

Nilotinib	Capsule 150 mg (as hydrochloride)	Oral	Ceahani	NM	MP NP	C19225	120	5	120
Nilotinib	Capsule 150 mg (as hydrochloride)	Oral	Ceahani	NM	MP	C19223	120	5	120
Nilotinib	Capsule 150 mg (as hydrochloride)	Oral	MSN-NILOTINIB	HK	MP NP	C19225	120	5	120
Nilotinib	Capsule 150 mg (as hydrochloride)	Oral	MSN-NILOTINIB	HK	MP	C19223	120	5	120
Nilotinib	Capsule 150 mg (as hydrochloride)	Oral	NILOTAS	CR	MP NP	C19225	120	5	120

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Nilotinib	Capsule 150 mg (as hydrochloride)	Oral	NILOTAS	CR	MP	C19223		120	5	120
Nilotinib	Capsule 150 mg (as hydrochloride)	Oral	Tasigna	NV	MP NP	C19225		120	5	120
Nilotinib	Capsule 150 mg (as hydrochloride)	Oral	Tasigna	NV	MP	C19223		120	5	120
Nilotinib	Capsule 200 mg (as hydrochloride)	Oral	Ceahani	NM	MP NP	C19225		120	5	120
Nilotinib	Capsule 200 mg (as hydrochloride)	Oral	Ceahani	NM	MP	C19223		120	5	120
Nilotinib	Capsule 200 mg (as hydrochloride)	Oral	MSN-NILOTINIB	HK	MP NP	C19225		120	5	120
Nilotinib	Capsule 200 mg (as hydrochloride)	Oral	MSN-NILOTINIB	HK	MP	C19223		120	5	120
Nilotinib	Capsule 200 mg (as hydrochloride)	Oral	NILOTAS	CR	MP NP	C19225		120	5	120
Nilotinib	Capsule 200 mg (as hydrochloride)	Oral	NILOTAS	CR	MP	C19223		120	5	120
Nilotinib	Capsule 200 mg (as hydrochloride)	Oral	Tasigna	NV	MP NP	C19225		120	5	120
Nilotinib	Capsule 200 mg (as hydrochloride)	Oral	Tasigna	NV	MP	C19223		120	5	120

[62] Schedule 1, Part 1, entries for Olmesartan in the form Tablet containing olmesartan medoxomil 20 mg

omit:

Olmesartan	Tablet containing olmesartan medoxomil 20 mg	Oral	APX-Olmesartan	TY	MP NP			30	5	30
Olmesartan	Tablet containing olmesartan medoxomil 20 mg	Oral	APX-Olmesartan	TY	MP NP		P14238	60	5	30

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[63] Schedule 1, Part 1, entries for Olmesartan in the form Tablet containing olmesartan medoxomil 40 mg

omit:

Olmesartan	Tablet containing olmesartan medoxomil 40 mg	Oral	APX-Olmesartan	TY	MP NP		30	5	30
Olmesartan	Tablet containing olmesartan medoxomil 40 mg	Oral	APX-Olmesartan	TY	MP NP	P14238	60	5	30

[64] Schedule 1, Part 1, entries for Olmesartan with hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 20 mg with hydrochlorothiazide 12.5 mg

omit:

Olmesartan with hydrochlorothiazide	Tablet containing olmesartan medoxomil 20 mg with hydrochlorothiazide 12.5 mg	Oral	APX-Olmesartan/HCTZ	TY	MP NP		30	5	30
Olmesartan with hydrochlorothiazide	Tablet containing olmesartan medoxomil 20 mg with hydrochlorothiazide 12.5 mg	Oral	APX-Olmesartan/HCTZ	TY	MP NP	P14238	60	5	30

[65] Schedule 1, Part 1, entries for Olmesartan with hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 12.5 mg

omit:

Olmesartan with hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 12.5 mg	Oral	APX-Olmesartan/HCTZ	TY	MP NP		30	5	30
Olmesartan with hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 12.5 mg	Oral	APX-Olmesartan/HCTZ	TY	MP NP	P14238	60	5	30

[66] Schedule 1, Part 1, entries for Olmesartan with hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 25 mg

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omit:

Olmesartan with hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 25 mg	Oral	APX-Olmesartan/HCTZ	TY	MP NP			30	5	30	
Olmesartan with hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 25 mg	Oral	APX-Olmesartan/HCTZ	TY	MP NP		P14238	60	5	30	

[67] Schedule 1, Part 1, after entry for Olsalazine in the form Tablet containing olsalazine sodium 500 mg

insert:

Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled pen	Injection	Omlyclo	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[68] Schedule 1, Part 1, after entry for Omalizumab in the form Injection 75 mg in 0.5 mL single dose pre-filled syringe *[Brand: Xolair]*

insert:

Omalizumab	Injection 150 mg in 1 mL single dose pre-filled pen	Injection	Omlyclo	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[69] Schedule 1, Part 1, after entry for Paclitaxel, nanoparticle albumin-bound *[Brand: Abraxane]*

insert:

Paclitaxel, nanoparticle albumin-bound	Powder for I.V. injection containing 100 mg paclitaxel	Injection	nab-Paclitaxel Accord	OC	MP	C4657 C6106 C6119		See Note 3	See Note 3	1	D(100)

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

(a) omit from the column headed "Circumstances": C18371

(b) omit from the column headed "Circumstances": C18450

[71] Schedule 1, Part 1, entry for Ponatinib in the form Tablet 15 mg (as hydrochloride) *[Maximum Quantity: 60; Number of Repeats: 5]*

(a) omit from the column headed "Circumstances": C17989 C18011 C18012 C18031 *substitute:* C19226 C19246 C19255

(b) omit from the column headed "Purposes": P17989 P18011 P18012 P18031 *substitute:* P19226 P19246 P19255

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[72] **Schedule 1, Part 1, entry for Ponatinib in the form Tablet 45 mg (as hydrochloride) *[Maximum Quantity: 30; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* C17989 C18011 C18012 C18031 *substitute:* C19226 C19246 C19255

(b) *omit from the column headed "Purposes":* P17989 P18011 P18012 P18031 *substitute:* P19226 P19246 P19255

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

(a) *omit from the column headed "Circumstances":* C17995

(b) *insert in numerical order in the column headed "Circumstances":* C19283

(c) *omit from the column headed "Purposes":* P17995

(d) *insert in numerical order in the column headed "Purposes":* P19283

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

(a) *omit from the column headed "Circumstances":* C17975

(b) *insert in numerical order in the column headed "Circumstances":* C19280

(c) *omit from the column headed "Purposes":* P17975

(d) *insert in numerical order in the column headed "Purposes":* P19280

[75] **Schedule 1, Part 1, after entry for Risedronic acid in the form Tablet containing risedronate sodium 150 mg *[Brand: APO-Risedronate; Maximum Quantity: 2; Number of Repeats: 5]***

insert:

Risedronic acid	Tablet containing risedronate sodium 150 mg	Oral	Risedronate Way	IX	MP NP	C6310 C6323 C6327	P6310 P6323 P6327	1	5	1
Risedronic acid	Tablet containing risedronate sodium 150 mg	Oral	Risedronate Way	IX	MP NP	C14234 C14235 C14263	P14234 P14235 P14263	2	5	1

[76] **Schedule 1, Part 1, entry for Sunitinib in the form Capsule 12.5 mg *[Brand: Sunitinib Sandoz; Authorised Prescriber: MP; Maximum Quantity: 28; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* C13152

(b) *insert in numerical order in the column headed "Circumstances":* C19250

(c) *omit from the column headed "Purposes":* P13152

(d) *insert in numerical order in the column headed "Purposes":* P19250

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[77] **Schedule 1, Part 1, entry for Sunitinib in the form Capsule 12.5 mg *[Brand: Sutent; Authorised Prescriber: MP; Maximum Quantity: 28; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* C13152

(b) *insert in numerical order in the column headed "Circumstances":* C19250

(c) *omit from the column headed "Purposes":* P13152

(d) *insert in numerical order in the column headed "Purposes":* P19250

[78] **Schedule 1, Part 1, entry for Sunitinib in the form Capsule 25 mg *[Brand: ARX-Sunitinib; Authorised Prescriber: MP; Maximum Quantity: 28; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* C13152

(b) *insert in numerical order in the column headed "Circumstances":* C19250

(c) *omit from the column headed "Purposes":* P13152

(d) *insert in numerical order in the column headed "Purposes":* P19250

[79] **Schedule 1, Part 1, entry for Sunitinib in the form Capsule 25 mg *[Brand: Sunitinib Sandoz; Authorised Prescriber: MP; Maximum Quantity: 28; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* C13152

(b) *insert in numerical order in the column headed "Circumstances":* C19250

(c) *omit from the column headed "Purposes":* P13152

(d) *insert in numerical order in the column headed "Purposes":* P19250

[80] **Schedule 1, Part 1, entry for Sunitinib in the form Capsule 25 mg *[Brand: Sutent; Authorised Prescriber: MP; Maximum Quantity: 28; Number of Repeats: 1]***

(a) *omit from the column headed "Circumstances":* C13152

(b) *insert in numerical order in the column headed "Circumstances":* C19250

(c) *omit from the column headed "Purposes":* P13152

(d) *insert in numerical order in the column headed "Purposes":* P19250

[81] **Schedule 1, Part 1, entry for Sunitinib in the form Capsule 37.5 mg *[Brand: ARX-Sunitinib; Authorised Prescriber: MP; Maximum Quantity: 28; Number of Repeats: 1]***

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(a) omit from the column headed "Circumstances": C13152

(b) insert in numerical order in the column headed "Circumstances": C19250

(c) omit from the column headed "Purposes": P13152

(d) insert in numerical order in the column headed "Purposes": P19250

[82] Schedule 1, Part 1, entry for Sunitinib in the form Capsule 37.5 mg *[Brand: Sunitinib Sandoz; Authorised Prescriber: MP; Maximum Quantity: 28; Number of Repeats: 1]*

(a) omit from the column headed "Circumstances": C13152

(b) insert in numerical order in the column headed "Circumstances": C19250

(c) omit from the column headed "Purposes": P13152

(d) insert in numerical order in the column headed "Purposes": P19250

[83] Schedule 1, Part 1, entry for Sunitinib in the form Capsule 37.5 mg *[Brand: Sutent; Authorised Prescriber: MP; Maximum Quantity: 28; Number of Repeats: 1]*

(a) omit from the column headed "Circumstances": C13152

(b) insert in numerical order in the column headed "Circumstances": C19250

(c) omit from the column headed "Purposes": P13152

(d) insert in numerical order in the column headed "Purposes": P19250

[84] Schedule 1, Part 1, entry for Sunitinib in the form Capsule 50 mg *[Brand: ARX-Sunitinib; Authorised Prescriber: MP; Maximum Quantity: 28; Number of Repeats: 1]*

(a) omit from the column headed "Circumstances": C13152

(b) insert in numerical order in the column headed "Circumstances": C19250

(c) omit from the column headed "Purposes": P13152

(d) insert in numerical order in the column headed "Purposes": P19250

[85] Schedule 1, Part 1, entry for Sunitinib in the form Capsule 50 mg *[Brand: Sunitinib Sandoz; Authorised Prescriber: MP; Maximum Quantity: 28; Number of Repeats: 1]*

(a) omit from the column headed "Circumstances": C13152

(b) insert in numerical order in the column headed "Circumstances": C19250

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(c) omit from the column headed "Purposes": P13152

(d) insert in numerical order in the column headed "Purposes": P19250

[86] Schedule 1, Part 1, entry for Sunitinib in the form Capsule 50 mg *[Brand: Sutent; Authorised Prescriber: MP; Maximum Quantity: 28; Number of Repeats: 1]*

(a) omit from the column headed "Circumstances": C13152

(b) insert in numerical order in the column headed "Circumstances": C19250

(c) omit from the column headed "Purposes": P13152

(d) insert in numerical order in the column headed "Purposes": P19250

[87] Schedule 1, Part 1, after entry for Tacrolimus in the form Capsule 5 mg (once daily prolonged release) *[Brand: Tacrolimus XR Sandoz; Maximum Quantity: 60; Number of Repeats: 3]*

insert:

Tacrolimus	Ointment 1 mg per g, 30 g	Application	aZematop	XT	MP NP	C19259		1	1	1	

[88] Schedule 1, Part 1, after entry for Tocilizumab in the form Concentrate for injection 80 mg in 4 mL

insert:

Tocilizumab	Concentrate for injection 80 mg in 4 mL	Injection	Avtozma	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)

[89] Schedule 1, Part 1, after entry for Tocilizumab in the form Concentrate for injection 200 mg in 10 mL

insert:

Tocilizumab	Concentrate for injection 200 mg in 10 mL	Injection	Avtozma	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)

[90] Schedule 1, Part 1, after entry for Tocilizumab in the form Concentrate for injection 400 mg in 20 mL

insert:

Tocilizumab	Concentrate for injection 400 mg in 20 mL	Injection	Avtozma	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)

[91] Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen *[Maximum Quantity: 4; Number*

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of Repeats: 5]

(a) omit from the column headed "Circumstances": C14195

(b) omit from the column headed "Circumstances": C18697 C18711

(c) insert in numerical order in the column headed "Circumstances": C18944 C18945 C18947 C19268

(d) omit from the column headed "Purposes": P14195

(e) omit from the column headed "Purposes": P18697 P18711

(f) insert in numerical order in the column headed "Purposes": P18944 P18945 P18947 P19268

[92] Schedule 1, Part 1, after entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled pen *[Maximum Quantity: 4; Number of Repeats: 6]*

insert:

Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled pen	Injection	Avtozma	EW	MP	C10560	P10560	4	0	4
Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled pen	Injection	Avtozma	EW	MP	C9477 C14094 C14121 C14182 C17709 C17748 C17760 C18639 C19002	P9477 P14094 P14121 P14182 P17709 P17748 P17760 P18639 P19002	4	1	4
Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled pen	Injection	Avtozma	EW	MP	C14084 C17710 C17742	P14084 P17710 P17742	4	2	4
Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled pen	Injection	Avtozma	EW	MP	C14080 C14147 C14175 C18534 C18562 C18565 C18584 C18601 C18604 C18638 C18661 C18670 C18696 C18948 C19004 C19027 C19041	P14080 P14147 P14175 P18534 P18562 P18565 P18584 P18601 P18604 P18638 P18661 P18670 P18696 P18948 P19004 P19027 P19041	4	3	4
Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled pen	Injection	Avtozma	EW	MP	C14088 C14499 C14507 C16725 C18938 C18939 C18944 C18945 C18947 C19036	P14088 P14499 P14507 P16725 P18938 P18939 P18944 P18945 P18947 P19036	4	5	4

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						C19268	P19268			
Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled pen	Injection	Avtozma	EW	MP	C9180 C19020	P9180 P19020	4	6	4

[93] Schedule 1, Part 1, entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe *[Maximum Quantity: 4; Number of Repeats: 5]*

(a) omit from the column headed "Circumstances": C14195

(b) omit from the column headed "Circumstances": C18697 C18711

(c) insert in numerical order in the column headed "Circumstances": C18944 C18945 C18947 C19268

(d) omit from the column headed "Purposes": P14195

(e) omit from the column headed "Purposes": P18697 P18711

(f) insert in numerical order in the column headed "Purposes": P18944 P18945 P18947 P19268

[94] Schedule 1, Part 1, after entry for Tocilizumab in the form Injection 162 mg in 0.9 mL single use pre-filled syringe *[Maximum Quantity: 4; Number of Repeats: 6]*

insert:

Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled syringe	Injection	Avtozma	EW	MP	C10560	P10560	4	0	4
Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled syringe	Injection	Avtozma	EW	MP	C9477 C14094 C14121 C14182 C17709 C17748 C17760 C18639 C19002	P9477 P14094 P14121 P14182 P17709 P17748 P17760 P18639 P19002	4	1	4
Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled syringe	Injection	Avtozma	EW	MP	C14084 C17710 C17742	P14084 P17710 P17742	4	2	4
Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled syringe	Injection	Avtozma	EW	MP	C14080 C14147 C14175 C18534 C18562 C18565 C18584 C18601 C18604 C18638 C18661 C18670 C18696 C18948 C19004 C19027 C19041	P14080 P14147 P14175 P18534 P18562 P18565 P18584 P18601 P18604 P18638 P18661 P18670 P18696 P18948 P19004 P19027 P19041	4	3	4

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Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled syringe	Injection	Avtozma	EW	MP	C14088 C14499 C14507 C16725 C18938 C18939 C18944 C18945 C18947 C19036 C19268	P14088 P14499 P14507 P16725 P18938 P18939 P18944 P18945 P18947 P19036 P19268	4	5	4	
Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled syringe	Injection	Avtozma	EW	MP	C9180 C19020	P9180 P19020	4	6	4	

[95] Schedule 1, Part 1, after entry for Tofacitinib in the form Tablet 10 mg *[Maximum Quantity: 56; Number of Repeats: 5]*

insert:

Tofersen	Solution for intrathecal injection 100 mg in 15 mL	Injection	Qalsody	BD	MP	C19261	P19261	1	2	1	D(100)
Tofersen	Solution for intrathecal injection 100 mg in 15 mL	Injection	Qalsody	BD	MP	C19237 C19253	P19237 P19253	1	5	1	D(100)
Tofersen	Solution for intrathecal injection 100 mg in 15 mL	Injection	Qalsody	BD	MP	C19231 C19243	P19231 P19243	1	6	1	D(100)

[96] Schedule 1, Part 1, entry for Triptorelin in the form Powder for I.M. injection (prolonged release) 3.75 mg (as embonate) with solvent, syringe and needles

omit from the column headed "Circumstances": C17812

[97] Schedule 1, Part 1, after entry for Varenicline in the form Box containing 11 tablets 0.5 mg and 42 tablets 1 mg *[Brand: Varenicline Viatris]*

insert:

Varenicline	Box containing 11 tablets 0.5 mg and 42 tablets 1 mg	Oral	VASSIX	NB	MP NP	C6871		1	0	1	

[98] Schedule 1, Part 1, after entry for Varenicline in the form Tablet 1 mg *[Brand: Varenicline Viatris; Maximum Quantity: 112; Number of Repeats: 0]*

insert:

Varenicline	Tablet 1 mg	Oral	VASSIX	NB	MP NP	C6885	P6885	56	2	56	

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Varenicline	Tablet 1 mg	Oral	VASSIX	NB	MP NP	C7483	P7483	112	0		56

[99] Schedule 1, Part 2, entries for Beclometasone

omit:

Beclometasone	Pressurised inhalation in breath actuated device containing beclometasone dipropionate 50 micrograms per dose, 200 doses (CFC-free formulation)	Inhalation by mouth	Qvar 50 Autohaler	IL	1

[100] Schedule 1, Part 2, omit entry for Insulin glulisine

[101] Schedule 1, Part 2, omit entry for Salbutamol

[102] Schedule 3, after entry for Responsible Person Code HJ

insert:

HK	SEED PHARMA PTY. LTD.	81 612 154 373

[103] Schedule 3, after entry for Responsible Person Code VK

insert:

VM	MSN LABORATORIES AUSTRALIA PTY LTD	78 686 372 716

[104] Schedule 3

omit:

VO	Avallon Pharmaceuticals Pty Limited	63 126 872 848

[105] Schedule 4, Part 1, omit entry for Circumstances Code “C10970”

[106] Schedule 4, Part 1, omit entry for Circumstances Code “C12524”

[107] Schedule 4, Part 1, omit entry for Circumstances Code “C12527”

[108] Schedule 4, Part 1, omit entry for Circumstances Code “C12529”

[109] Schedule 4, Part 1, omit entry for Circumstances Code “C12541”

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[110] Schedule 4, Part 1, omit entry for Circumstances Code "C12543"

[111] Schedule 4, Part 1, omit entry for Circumstances Code "C12549"

[112] Schedule 4, Part 1, omit entry for Circumstances Code "C12557"

[113] Schedule 4, Part 1, omit entry for Circumstances Code "C12561"

[114] Schedule 4, Part 1, omit entry for Circumstances Code "C12569"

[115] Schedule 4, Part 1, omit entry for Circumstances Code "C12570"

[116] Schedule 4, Part 1, omit entry for Circumstances Code "C13152"

[117] Schedule 4, Part 1, omit entry for Circumstances Code "C13950"

[118] Schedule 4, Part 1, omit entry for Circumstances Code "C14195"

[119] Schedule 4, Part 1, entry for Circumstances Code "C14582"

substitute:

C14582	P14582	CN14582	Etanercept	Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition. AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition	Compliance with Authority Required procedures

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has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; OR

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

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

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

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				used to determine response. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

[120] Schedule 4, Part 1, entry for Circumstances Code "C14590"

substitute:

C14590	P14590	CN14590	Adalimumab	Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L	Compliance with Authority Required procedures

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	or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records. An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

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[121] Schedule 4, Part 1, omit entry for Circumstances Code "C16479"

[122] Schedule 4, Part 1, entry for Circumstances Code "C16709"

substitute:

C16709	P16709	CN16709	Etanercept	Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; OR (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or	Compliance with Written Authority Required procedures

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		(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription, AND (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

[123] Schedule 4, Part 1, omit entry for Circumstances Code “C17073”

[124] Schedule 4, Part 1, omit entry for Circumstances Code “C17113”

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[125] **Schedule 4, Part 1, omit entry for Circumstances Code "C17579"**

[126] **Schedule 4, Part 1, omit entry for Circumstances Code "C17822"**

[127] **Schedule 4, Part 1, omit entry for Circumstances Code "C17829"**

[128] **Schedule 4, Part 1, omit entry for Circumstances Code "C17830"**

[129] **Schedule 4, Part 1, omit entry for Circumstances Code "C17833"**

[130] **Schedule 4, Part 1, omit entry for Circumstances Code "C17889"**

[131] **Schedule 4, Part 1, omit entry for Circumstances Code "C17895"**

[132] **Schedule 4, Part 1, omit entry for Circumstances Code "C17907"**

[133] **Schedule 4, Part 1, omit entry for Circumstances Code "C17922"**

[134] **Schedule 4, Part 1, omit entry for Circumstances Code "C17975"**

[135] **Schedule 4, Part 1, omit entry for Circumstances Code "C17989"**

[136] **Schedule 4, Part 1, omit entry for Circumstances Code "C17995"**

[137] **Schedule 4, Part 1, omit entry for Circumstances Code "C18010"**

[138] **Schedule 4, Part 1, omit entry for Circumstances Code "C18011"**

[139] **Schedule 4, Part 1, omit entry for Circumstances Code "C18012"**

[140] **Schedule 4, Part 1, omit entry for Circumstances Code "C18031"**

[141] **Schedule 4, Part 1, entry for Circumstances Code "C18333"**

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

[142] **Schedule 4, Part 1, omit entry for Circumstances Code "C18371"**

[143] **Schedule 4, Part 1, omit entry for Circumstances Code "C18450"**

[144] **Schedule 4, Part 1, omit entry for Circumstances Code "C18480"**

[145] **Schedule 4, Part 1, entry for Circumstances Code "C18562"**

substitute:

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C18562	P18562	CN18562	Adalimumab Baricitinib Tocilizumab Tofacitinib Upadacitinib	Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, AND Patient must not receive more than 16 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; OR (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break	Compliance with Written Authority Required procedures

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				of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

[146] Schedule 4, Part 1, entry for Circumstances Code "C18598"

substitute:

C18598	P18598	CN18598	Certolizumab pegol	Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist; OR	Compliance with Written Authority Required procedures

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	Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; OR (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with

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				the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription, AND (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

[147] Schedule 4, Part 1, entry for Circumstances Code "C18635"

substitute:

C18635	P18635	CN18635	Abatacept Golimumab	Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Must be treated by a rheumatologist. or Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition. or	Compliance with Written Authority Required procedures

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	Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication. AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition. AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times. AND Patient must not receive more than 16 weeks of treatment under this restriction. AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be at least 18 years of age. Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores. Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; OR (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course	

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	of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription, AND (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 3 repeats. Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 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. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

[148] Schedule 4, Part 1, omit entry for Circumstances Code "C18697"

[149] Schedule 4, Part 1, omit entry for Circumstances Code "C18711"

[150] Schedule 4, Part 1, after entry for Circumstances Code "C18931"

insert:

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C18938	P18938	CN18938	Tocilizumab	Severe active rheumatoid arthritis First continuing treatment - balance of supply Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.	Compliance with Authority Required procedures - Streamlined Authority Code 18938
C18939	P18939	CN18939	Tocilizumab	Severe active juvenile idiopathic arthritis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, AND Patient must have demonstrated an adequate response to treatment with this drug, AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total	Compliance with Authority Required procedures - Streamlined Authority Code 18939

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				number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.	
C18944	P18944	CN18944	Tocilizumab	Severe active juvenile idiopathic arthritis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND Patient must have demonstrated an adequate response to treatment with this drug, AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; OR (b) a reduction in the active (swollen and tender) joint count by at least 50% from	Compliance with Written Authority Required procedures

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	baseline; OR (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription, AND (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

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C18945	P18945	CN18945	Tocilizumab	Severe active juvenile idiopathic arthritis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, AND Patient must have demonstrated an adequate response to treatment with this drug, AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; OR (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; OR (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription, AND (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment	Compliance with Written Authority Required procedures

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				of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide sufficient doses for up to 24 weeks treatment. Up to a maximum of 5 repeats will be authorised. Where fewer than 5 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment with this drug may be requested through the balance of supply restriction.	
C18947	P18947	CN18947	Tocilizumab	Severe active juvenile idiopathic arthritis Balance of supply - Continuing treatment Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of	Compliance with Authority Required procedures

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				rheumatoid arthritis.	
C18948	P18948	CN18948	Tocilizumab	Severe active rheumatoid arthritis Initial treatment - Initial 1 (new patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, AND Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and	Compliance with Authority Required procedures

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	documented in the patient's medical records. The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity. The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months. If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records. The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to prior treatment must be documented in the patient's medical records. The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:	

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				(a) the active joint count, ESR and/or CRP result and date of results; (b) details of prior treatment, including dose and date/duration of treatment. (c) If applicable, details of any contraindications/intolerances. (d) If applicable, the maximum tolerated dose of methotrexate. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	

[151] Schedule 4, Part 1, after entry for Circumstances Code "C18999"

insert:

C19002	P19002	P19002	Tocilizumab	Severe active juvenile idiopathic arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab) Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, AND Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab. Must be treated by a paediatric rheumatologist; OR Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre. Patient must be under 18 years of age. Patients under 30 kg may receive up to 24 weeks of treatment under this restriction. Patients 30 kg and over may receive up to 16 weeks of treatment under this restriction. If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must	Compliance with Authority Required procedures

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				note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). 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 who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.	
C19004	P19004	CN19004	Tocilizumab	Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of	Compliance with Authority Required procedures

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	tocilizumab) Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, AND Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An 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

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				patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	

[152] Schedule 4, Part 1, after entry for Circumstances Code "C19016"

insert:

C19020	P19020	CN19020	Tocilizumab	Active giant cell arteritis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND The treatment must not exceed 52 weeks in total including initial and continuing applications. Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis.	Compliance with Authority Required procedures - Streamlined Authority Code 19020

[153] Schedule 4, Part 1, after entry for Circumstances Code "C19021"

insert:

C19027	P19027	CN19027	Tocilizumab	Severe active rheumatoid arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of	Compliance with Authority Required procedures

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rheumatoid arthritis.

Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

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

Where the baseline active joint count is based on total active joints (i.e. more than 20

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				active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.	

[154] Schedule 4, Part 1, after entry for Circumstances Code "C19035"

insert:

C19036	P19036	CN19036	Tocilizumab	Severe active rheumatoid arthritis First continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, AND Patient must have demonstrated an adequate response to treatment with this drug, AND Patient must not receive more than 24 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease	Compliance with Authority Required procedures - Streamlined Authority Code 19036

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				and not irreversible damage such as joint destruction or bony overgrowth). The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the prescribing. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.	

[155] Schedule 4, Part 1, after entry for Circumstances Code "C19038"

insert:

C19041	P19041	CN19041	Tocilizumab	Severe active rheumatoid arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, AND Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, AND Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, AND The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, AND Patient must not receive more than 16 weeks of treatment under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of	Compliance with Authority Required procedures

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	rheumatoid arthritis. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response. The following information must be provided by the prescriber at the time of application and documented in the patient's medical records: (a) the active joint count, ESR and/or CRP result and date of result; (b) the most recent biological agent and the date of the last continuing prescription. (c) If applicable, the new baseline scores. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

[156] Schedule 4, Part 1, omit entry for Circumstances Code "C19201"

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[157] Schedule 4, Part 1, omit entry for Circumstances Code "C19202"

[158] Schedule 4, Part 1, after entry for Circumstances Code "C19222"

insert:

C19223	P19223	CN19223	Dasatinib Imatinib Nilotinib	Chronic Myeloid Leukaemia (CML) Initial treatment Patient must have a primary diagnosis of chronic myeloid leukaemia, AND Patient must not have previously experienced an inadequate response to PBS-subsidised treatment with this drug for this condition, AND The treatment must be the sole PBS-subsidised therapy for this condition. A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.	Compliance with Authority Required procedures
C19225	P19225	CN19225	Dasatinib Imatinib Nilotinib	Chronic Myeloid Leukaemia (CML) Continuing treatment Patient must have received initial PBS-subsidised treatment with this drug for this condition, AND Patient must be responding to treatment with this drug for this condition, AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a medical practitioner. OR Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine.	Compliance with Authority Required procedures - Streamlined Authority Code 19225
C19226	P19226	CN19226	Ponatinib	Chronic Myeloid Leukaemia (CML) Continuing treatment Patient must have received initial PBS-subsidised treatment with this drug for this condition, AND Patient must have demonstrated a major cytogenic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR Patient must have demonstrated a peripheral blood level of BCR-ABL of less than 1% on the international scale in the preceding 18 months and thereafter at 12 monthly intervals, AND	Compliance with Written Authority Required procedures

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				The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a medical practitioner. OR Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine. A pathology report demonstrating the patient's cytogenetic response or a peripheral blood level of BCR-ABL must be documented in the patient's medical records.	
C19231	P19231	CN19231	Tofersen	Amyotrophic lateral sclerosis Initial treatment Patient must have/have had one or more clinical symptoms of amyotrophic lateral sclerosis prior to commencing treatment with this drug, AND The condition must have been diagnosed by a neurologist, AND The condition must have a confirmed pathogenic (class 5) or likely pathogenic (class 4) superoxide dismutase 1 (SOD1) gene variant, AND Patient must not have undergone a tracheostomy, AND Patient must not have experienced respiratory failure, AND The treatment must be given concomitantly with best supportive care (including riluzole where appropriate) for this condition, AND Patient must not be receiving concomitant treatment with edaravone for this condition. Must be treated by a specialist with expertise in the diagnosis and management of amyotrophic lateral sclerosis. The following must be documented in the patient's medical records: a) date and details of the patient's genetic testing confirming the presence of the SOD1 pathogenic gene variant, AND b) baseline score of Amyotrophic Lateral Sclerosis Functional Rating Scale - Revised (ALSFRS-R) at treatment initiation.	Compliance with Authority Required procedures
C19234	P19234	CN19234	Asciminib	Chronic Myeloid Leukaemia (CML) Continuing treatment for patients without T315I mutation Patient must have received initial PBS-subsidised treatment with this drug for this condition, AND Patient must be undergoing first continuing treatment with this drug, demonstrating either (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%; OR Patient must be undergoing subsequent continuing treatment with this drug, demonstrating a response at 12-monthly intervals of either: (i) a major cytogenetic response (ii) a peripheral blood level of BCR-ABL of less than 1%, AND	Compliance with Authority Required procedures - Streamlined Authority Code 19234

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				The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a medical practitioner. OR Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine.	
C19236	P19236	CN19236	Dupilumab	Uncontrolled severe asthma Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy), Initial treatment - Initial 2 (Change of treatment), Continuing treatment - Balance of Supply in a patient aged 6 to 12 years Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy) restriction to complete 32 weeks of treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 2 (Change of treatment) restriction to complete 32 weeks of treatment; OR Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, AND The treatment must provide no more than the balance of up to 32 weeks treatment available under the Initial 1 and Initial 2 restriction; OR The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing restriction. Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.	Compliance with Authority Required procedures
C19237	P19237	CN19237	Tofersen	Amyotrophic lateral sclerosis Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the first continuing treatment, the extended first continuing treatment or the grandfather treatment restriction, AND Patient must have demonstrated an adequate response to treatment defined as any improvement or stabilisation in the ALSFRS-R score (i.e. no more than a 20% decline from the baseline ALSFRS-R score), if they have received treatment under the first continuing or extended first continuing restriction; OR Patient must have demonstrated a clinical benefit from treatment, based on clinician judgment, within 12 months of treatment initiation, if they have received treatment	Compliance with Authority Required procedures

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				under the grandfather listing, AND Patient must not have undergone a tracheostomy, AND Patient must not have experienced respiratory failure, AND Patient must not be receiving palliative (end of life) care, AND The treatment must be given concomitantly with best supportive care (including riluzole where appropriate) for this condition, AND Patient must not be receiving concomitant treatment with edaravone for this condition. Must be treated by a specialist with expertise in the diagnosis and management of amyotrophic lateral sclerosis.	
C19243	P19243	CN19243	Tofersen	Amyotrophic lateral sclerosis First continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, AND Patient must not have undergone a tracheostomy, AND Patient must not have experienced respiratory failure, AND Patient must not be receiving palliative (end of life) care, AND The treatment must be given concomitantly with best supportive care (including riluzole where appropriate) for this condition, AND Patient must not be receiving concomitant treatment with edaravone for this condition. Must be treated by a specialist with expertise in the diagnosis and management of amyotrophic lateral sclerosis. Assessment of response must be conducted after 6 months of the first continuing treatment (i.e. at 12 months from treatment initiation). If a response to treatment cannot be demonstrated at this assessment, prescribers may apply for up to a maximum of three months (i.e. 2 repeats) of additional continuing treatment under the extended first continuing treatment phase to verify non-response. Reassessment of response must be conducted after the additional three months of therapy to determine the patient's eligibility for further treatment. If this reassessment is not undertaken, the patient will not be eligible for ongoing treatment. All the assessments of response must be documented in the patient's medical records. Adequate response to treatment is defined as any improvement or stabilisation (no more than 20% decline) from baseline score of ALSFRS-R.	Compliance with Authority Required procedures

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C19246	P19246	CN19246	Ponatinib	Chronic Myeloid Leukaemia (CML) Initial PBS-subsidised treatment for patients with T315I mutation Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report, AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a medical practitioner. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; OR (ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale, AND (iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription, AND (ii) 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). Up to a maximum of 18 months of treatment may be authorised under this initial restriction.	Compliance with Written Authority Required procedures
C19250	P19250	CN19250	Sunitinib	Metastatic or unresectable malignant gastrointestinal stromal tumour Initial treatment The condition must not be resectable, AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, AND Patient must have a WHO performance status of 2 or less, AND Patient must have previously failed or be intolerant to imatinib mesilate. Applications for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription, AND	Compliance with Written Authority Required procedures

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				(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). Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.	
C19252	P19252	CN19252	Edaravone	Amyotrophic lateral sclerosis Initial treatment The condition must be/have been diagnosed by a neurologist, AND Patient must not have had symptoms for more than 2 years prior to commencing therapy with this drug, AND Patient must have at least 80 percent of predicted forced vital capacity (FVC) or slow vital capacity (SVC) within the 2 months prior to commencing therapy with this drug, AND Patient must not require assistance with eating or ambulation prior to commencing treatment with this drug, AND Patient must have at least two points on each individual item of the ALS Functional Rating Scale - Revised (ALSFRS-R) score prior to commencing therapy with this drug, AND Patient must not have undergone a tracheostomy, AND Patient must not have experienced respiratory failure, AND Patient must not be receiving concomitant treatment with tofersen for this condition. The date of diagnosis, the date and results of spirometry (in terms of percent of predicted forced vital capacity or slow vital capacity) must be supplied with the initial authority application. Prescribers must request a quantity sufficient to cover one month per dispensing, in accordance with the patient's treatment cycle. Prescribers must request a smaller number of units than the listed maximum quantity units if it is adequate for the patient's needs.	Compliance with Authority Required procedures
C19253	P19253	CN19253	Tofersen	Amyotrophic lateral sclerosis Grandfather arrangements - Transitioning from non-PBS to PBS-subsidised treatment Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 October 2026, AND Patient must have had one or more clinical symptoms of amyotrophic lateral sclerosis prior to commencing non-PBS-subsidised treatment with this drug, AND The condition must have been diagnosed by a neurologist, AND The condition must have a confirmed pathogenic (class 5) or likely pathogenic (class	Compliance with Authority Required procedures

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				4) superoxide dismutase 1 (SOD1) gene variant, AND Patient must not have undergone a tracheostomy, AND Patient must not have experienced respiratory failure, AND Patient must not be receiving palliative (end of life) care, AND The treatment must be given concomitantly with best supportive care (including riluzole where appropriate) for this condition, AND Patient must not be receiving concomitant treatment with edaravone for this condition. Must be treated by a specialist with expertise in the diagnosis and management of amyotrophic lateral sclerosis. The date and details of the patient's genetic testing confirming the presence of the SOD1 pathogenic gene variant must be documented in the patient's medical records. 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 Subsequent continuing treatment criteria.	
C19255	P19255	CN19255	Ponatinib	Chronic Myeloid Leukaemia (CML) Initial PBS-subsidised treatment for patients without T315I mutation Patient must have experienced an inadequate response to an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; OR Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal, AND Patient must have experienced an inadequate response to an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority; OR Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal, AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a medical practitioner. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; OR (ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale, AND	Compliance with Written Authority Required procedures

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				(iii) where there has been a loss of response to dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement. All reports must be documented in the patient's medical records If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription, AND (ii) 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). Up to a maximum of 18 months of treatment may be authorised under this initial restriction.	
C19259	P19259	CN19259	Tacrolimus	Moderate to severe atopic dermatitis Flare treatment Patient must have 1 or more of the following contraindications to topical corticosteroids: (i) perioral dermatitis; (ii) periorbital dermatitis; (iii) rosacea; (iv) epidermal atrophy; (v) dermal atrophy; (vi) allergy to topical corticosteroids; (vii) cataracts; (viii) glaucoma; (ix) raised intraocular pressure. OR The condition must not have been adequately controlled with topical corticosteroid therapy. Inadequate control of this condition with topical corticosteroid therapy is defined as: (i) no clearance of the skin despite at least 2 weeks of a potent topical corticosteroid for the body or a mild topical corticosteroid for the face and eyelids, applied every day; OR (ii) clearing of the skin with at least 2 weeks of a potent topical corticosteroid for the body or a mild topical corticosteroid for the face and eyelids, applied every day, but almost immediate and significant flare in disease (within 48 hours) upon stopping topical corticosteroids, occurring on at least 2 consecutive occasions. Treatment should be discontinued, and further treatment options should be considered if no signs of improvement are seen after 2 weeks of treatment. Once clearance or near clearance of atopic dermatitis is achieved, patients should cease tacrolimus treatment and reinitiate only if there is a flare of their atopic dermatitis that meets the PBS eligibility criteria.	Compliance with Authority Required procedures
C19260	P19260	CN19260	Asciminib	Chronic Myeloid Leukaemia (CML) Initial PBS-subsidised treatment for patients without T315I mutation The condition must not be in the blast phase, AND Patient must have experienced an inadequate response to an adequate trial of at least	Compliance with Authority Required procedures

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				two tyrosine kinase inhibitors; OR Patient must have experienced intolerance, not an inadequate response, to at least two tyrosine kinase inhibitors; OR Patient must have experienced an inadequate response to an adequate trial of at least one tyrosine kinase inhibitor with intolerance to at least another tyrosine kinase inhibitor, AND The treatment must be the sole PBS-subsidised therapy for this condition. Blast phase defined according to the latest WHO criteria. A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.	
C19261	P19261	CN19261	Tofersen	Amyotrophic lateral sclerosis Extended first continuing treatment (additional 3 doses) Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, AND Patient must not have demonstrated an adequate response to treatment with this drug for this condition, AND Patient must not have undergone a tracheostomy, AND Patient must not have experienced respiratory failure, AND Patient must not be receiving palliative (end of life) care, AND The treatment must be given concomitantly with best supportive care (including riluzole where appropriate) for this condition, AND Patient must not be receiving concomitant treatment with edaravone for this condition. Must be treated by a specialist with expertise in the diagnosis and management of amyotrophic lateral sclerosis. Reassessment of response must be conducted after the additional three months of therapy to determine the patient's eligibility for further treatment. If this reassessment is not undertaken, the patient will not be eligible for ongoing treatment. All the assessments of response must be documented in the patient's medical records. Patient may qualify for this treatment phase once only. Adequate response to treatment is defined as any improvement or stabilisation (no more than 20% decline) from baseline score of ALSFRS-R.	Compliance with Authority Required procedures

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C19267	P19267	CN19267	Edaravone	Amyotrophic lateral sclerosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND Patient must not have undergone a tracheostomy, AND Patient must not have experienced respiratory failure, AND Patient must not be receiving concomitant treatment with tofersen for this condition.	Compliance with Authority Required procedures
C19268	P19268	CN19268	Tocilizumab	Active giant cell arteritis Initial treatment Must be treated by a rheumatologist, clinical immunologist or neurologist experienced in the management of giant cell arteritis. Patient must have clinical symptoms of active giant cell arteritis in the absence of any other identifiable cause, AND Patient must have an ESR equal to or greater than 30 mm/hour within the past 6 weeks; OR Patient must have a CRP equal to or greater than 10 mg/L within the past 6 weeks; OR Patient must have active giant cell arteritis confirmed by positive temporal artery biopsy or imaging, AND Patient must have had a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis, AND Patient must have had temporal artery biopsy revealing features of giant cell arteritis at diagnosis; OR Patient must have had evidence of large-vessel vasculitis by magnetic resonance (MR) or computed tomography (CT) angiography or PET/CT at diagnosis; OR Patient must have had evidence of positive temporal artery halo sign by ultrasound (US) at diagnosis, AND The treatment must be in combination with a tapering course of corticosteroids, AND The treatment must not exceed 52 weeks in total including initial and continuing applications. Patient must be aged 50 years or older. Clinical symptoms of giant cell arteritis at diagnosis include unequivocal cranial symptoms of giant cell arteritis (new onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia related vision loss, or otherwise unexplained mouth or jaw pain upon mastication); or symptoms of polymyalgia rheumatica, defined as shoulder and/or hip girdle pain associated with inflammatory morning stiffness.	Compliance with Written Authority Required procedures

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				The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS and must include: (a) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has active giant cell arteritis including pathology reports outlining the patient's ESR or CRP levels within the last 6 weeks, or positive temporal artery biopsy or imaging, AND (b) details (dates, results, and unique identifying number/code or provider number) of evidence that the patient has been diagnosed with giant cell arteritis with a history of an ESR equal to or greater than 50 mm/hour or a CRP equal to or greater than 24.5 mg/L at diagnosis. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription, AND (ii) 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).	
C19277	P19277	CN19277	Asciminib	Chronic Myeloid Leukaemia (CML) Initial PBS-subsidised treatment for patients with T315I mutation The condition must not be in the blast phase, AND Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report, AND The condition must be expressing the Philadelphia chromosome confirmed through cytogenetic analysis; OR The condition must have the transcript BCR-ABL tyrosine kinase confirmed through quantitative polymerase chain reaction (PCR), AND Patient must have experienced an inadequate response to an adequate trial of at least one tyrosine kinase inhibitor as confirmed through a pathology report from an Approved Pathology Authority; OR Patient must have experienced intolerance, not an inadequate response, to at least one tyrosine kinase inhibitor, AND The treatment must be the sole PBS-subsidised therapy for this condition. Must be treated by a medical practitioner. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; OR	Compliance with Written Authority Required procedures

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				(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale, AND (iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation, AND (iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) details of the proposed prescription, AND (ii) 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). Patients are eligible for PBS-subsidised treatment with only one of imatinib, dasatinib, nilotinib, ponatinib or asciminib at any one time and must not be receiving concomitant interferon alfa therapy Up to a maximum of 18 months of treatment may be authorised under this initial restriction. Blast phase defined according to the latest WHO criteria. A pathology cytogenetic report from an Approved Pathology Authority conducted on peripheral blood or bone marrow supporting the diagnosis of chronic myeloid leukaemia to confirm eligibility for treatment, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records.	
C19280	P19280	CN19280	Ribociclib	Early breast cancer The treatment must be adjuvant to surgical resection, AND Patient must have been untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy at the time non-PBS-subsidised or PBS-subsidised treatment was initiated; OR Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, AND The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing a CDK4/6 inhibitor therapy for this condition, AND The condition must be human epidermal growth factor receptor 2 (HER2) negative, AND	Compliance with Authority Required procedures

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				The condition must be hormone receptor positive, AND The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system), AND The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 3 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression, AND The treatment must not be in combination with any of the following: (i) abemaciclib, (ii) olaparib, (iii) pembrolizumab. Must be treated by a medical practitioner; OR Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine, AND Patient must be undergoing concurrent treatment with a non-steroidal aromatase inhibitor where this drug is being prescribed as a PBS benefit. Retain all pathology imaging and investigative test results in the patient's medical records. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C19282	P19282	CN19282	Abemaciclib	Early breast cancer The treatment must be adjuvant to surgical resection, AND Patient must have been untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy at the time non-PBS-subsidised or PBS-subsidised treatment was initiated; OR Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, AND The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing a CDK4/6 inhibitor therapy for this condition, AND The condition must be human epidermal growth factor receptor 2 (HER2) negative, AND The condition must be hormone receptor positive, AND The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading	Compliance with Authority Required procedures

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				system), AND The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 2 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression, AND The treatment must not be in combination with any of the following: (i) olaparib, (ii) pembrolizumab, (iii) ribociclib. Patient must be undergoing concurrent treatment with endocrine therapy where this drug is being prescribed as a PBS benefit, AND Must be treated by a medical practitioner. OR Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine. Retain all pathology imaging and investigative test results in the patient's medical records. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).	
C19283	P19283	CN19283	Ribociclib	Early breast cancer The treatment must be adjuvant to surgical resection, AND Patient must have been untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy at the time non-PBS-subsidised or PBS-subsidised treatment was initiated; OR Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal, AND The condition must not have been treated with adjuvant endocrine therapy for more than 6 months prior to commencing a CDK4/6 inhibitor therapy for this condition, AND The condition must be human epidermal growth factor receptor 2 (HER2) negative, AND The condition must be hormone receptor positive, AND The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system), AND The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 3 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression, AND	Compliance with Authority Required procedures

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	The treatment must not be in combination with any of the following: (i) abemaciclib, (ii) olaparib, (iii) pembrolizumab, AND Patient must require dosage reduction requiring a pack of 21 tablets. Patient must be undergoing concurrent treatment with a non-steroidal aromatase inhibitor where this drug is being prescribed as a PBS benefit, AND Must be treated by a medical practitioner. OR Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine. Retain all pathology imaging and investigative test results in the patient's medical records. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under locally advanced or metastatic disease is no longer available).

[159] Schedule 5, entry for Adalimumab in the form Injection 20 mg in 0.2 mL pre-filled syringe

insert in the column headed "Brand" after entry for the brand "Humira": Yuflyma

[160] Schedule 5, entry for Allopurinol *[GRP-980]*

omit from the column headed "Brand": NOUMED ALLOPURINOL

[161] Schedule 5, entry for Apixaban *[GRP-31009]*

(a) insert in the column headed "Brand" after entry for the brand "Apixaban-APX": Apixaban Dr.Reddy's

(b) insert in the column headed "Brand" after entry for the brand "Eliquis": MSN-APIXABAN

[162] Schedule 5, entry for Apixaban *[GRP-31011]*

(a) insert in the column headed "Brand" after entry for the brand "Apexa": Apixaban Dr.Reddy's

(b) insert in the column headed "Brand" after entry for the brand "Eliquis": MSN-APIXABAN

[163] Schedule 5, entry for Apixaban *[GRP-31028]*

(a) insert in the column headed "Brand" after entry for the brand "Apixaban-APX": Apixaban Dr.Reddy's

(b) insert in the column headed "Brand" after entry for the brand "Apixaban Sandoz": Apixaban Viatris

(c) insert in the column headed "Brand" after entry for the brand "Eliquis": MSN-APIXABAN

[164] Schedule 5, entry for Apixaban *[GRP-31030]*

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(a) *insert in the column headed "Brand" after entry for the brand "Apixaban-APX":* Apixaban Dr.Reddy's

(b) *insert in the column headed "Brand" after entry for the brand "Apixaban Sandoz":* Apixaban Viatris

(c) *insert in the column headed "Brand" after entry for the brand "Eliquis":* MSN-APIXABAN

[165] Schedule 5, entry for Cefuroxime

insert as the first entry in the column headed "Brand": ARX-Cefuroxime

[166] Schedule 5, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4

omit from the column headed "Brand": Nepexto

[167] Schedule 5, entry for Gabapentin *[GRP-1081]*

(a) *insert as the first entry in the column headed "Brand":* APX-GABAPENTIN

(b) *omit from the column headed "Brand":* Gabapentin APOTEX

[168] Schedule 5, entry for Guanfacine *[GRP-31050]*

insert as the first entry in the column headed "Brand": Guanfacine MHC

[169] Schedule 5, entry for Guanfacine *[GRP-31052]*

insert as the first entry in the column headed "Brand": Guanfacine MHC

[170] Schedule 5, entry for Guanfacine *[GRP-31054]*

insert as the first entry in the column headed "Brand": Guanfacine MHC

[171] Schedule 5, entry for Guanfacine *[GRP-31056]*

insert as the first entry in the column headed "Brand": Guanfacine MHC

[172] Schedule 5, omit entry for Lenalidomide

[173] Schedule 5, entry for Levetiracetam *[GRP-688]*

omit from the column headed "Brand": Levetiracetam Mylan

[174] Schedule 5, after entry for Nicorandil *[GRP-16153]*

insert:

Nilotinib	GRP-30979	Capsule 150 mg (as hydrochloride)	Oral	Ceahani MSN-NILOTINIB

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				NILOTAS Tasigna
Nilotinib	GRP-30981	Capsule 200 mg (as hydrochloride)	Oral	Ceahani MSN-NILOTINIB NILOTAS Tasigna

[175] Schedule 5, entry for Olmesartan *[GRP-21125]*

omit from the column headed "Brand": APX-Olmesartan

[176] Schedule 5, entry for Olmesartan *[GRP-21127]*

omit from the column headed "Brand": APX-Olmesartan

[177] Schedule 5, entry for Olmesartan with hydrochlorothiazide *[GRP-21129]*

omit from the column headed "Brand": APX-Olmesartan/HCTZ

[178] Schedule 5, entry for Olmesartan with hydrochlorothiazide *[GRP-21131]*

omit from the column headed "Brand": APX-Olmesartan/HCTZ

[179] Schedule 5, entry for Olmesartan with hydrochlorothiazide *[GRP-21133]*

omit from the column headed "Brand": APX-Olmesartan/HCTZ

[180] Schedule 5, entry for Omalizumab in the form Injection 75 mg in 0.5 mL single dose pre-filled pen

insert as the first entry in the column headed "Brand": Omlyclo

[181] Schedule 5, entry for Omalizumab in the form Injection 150 mg in 1 mL single dose pre-filled pen

insert as the first entry in the column headed "Brand": Omlyclo

[182] Schedule 5, entries for Oxycodone

omit:

Oxycodone	GRP-23904	Tablet containing oxycodone hydrochloride 5 mg	Oral	ENDONE Oxycodone Viatris

[183] Schedule 5, entry for Risedronic acid *[GRP-6695]*

insert in the column headed "Brand" after entry for the brand "APO-Risedronate": Risedronate Way

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[184] Schedule 5, entries for Salbutamol

omit:

Salbutamol	GRP-921	Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20	Inhalation	Ventolin Nebules
Salbutamol	GRP-921	Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 30	Inhalation	Salbutamol Cipla

[185] Schedule 5, after entry for Tobramycin

insert:

Tocilizumab	GRP-25598	Concentrate for injection 200 mg in 10 mL	Injection	Actemra Avtozma
Tocilizumab	GRP-25599	Concentrate for injection 400 mg in 20 mL	Injection	Actemra Avtozma
Tocilizumab	GRP-25600	Concentrate for injection 80 mg in 4 mL	Injection	Actemra Avtozma
Tocilizumab	GRP-31057	Injection 162 mg in 0.9 mL single use pre-filled pen	Injection	Actemra ACTPen Avtozma
Tocilizumab	GRP-31058	Injection 162 mg in 0.9 mL single use pre-filled syringe	Injection	Actemra Subcutaneous Injection Avtozma

[186] Schedule 5, entry for Varenicline *[GRP-26236]*

insert in the column headed "Brand" after entry for the brand "Varenicline Viatris": VASSIX

[187] Schedule 5, entry for Varenicline *[GRP-27902]*

insert in the column headed "Brand" after entry for the brand "Varenicline Viatris": VASSIX

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