PB 138 of 2024

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

National Health Act 1953

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

Dated 19 December 2024

EDEN SIMON
Assistant Secretary (Acting)
Pricing and PBS Policy Branch
Technology Assessment and Access Division

Contents

1. Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (January Update) Instrument 2024*.

(2) This Instrument may also be cited as PB 138 of 2024.

2. Commencement

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

Commencement Information

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

Note: This table relates only to the provisions of this instrument as originally made.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

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

3. Authority

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

4. Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

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

[1] Schedule 1, Part 1, entries for Abacavir with lamivudine

omit:

Abacavir with lamivudine	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg	Oral	Abacavir/Lamivudine AF Mylan	MP NP	C4527 C4528		60	5	30	D(100)

[2] Schedule 1, Part 1, after entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Brand: Humira; Maximum Quantity: 6; Number of Repeats: 0]*

insert:

Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11713 C15473	P11713 P15473	2	0	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C12120 C14061 C14063 C14064 C14107 C14136	See Note 3	See Note 3	See Note 3	2	C(100)
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609	2	2	2	
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C9064 C9386 C11861 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673	P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673	2	3	2	

Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11107 C12155 C12212 C13556 C13612 C14377 C14378	P11107 P12155 P12212 P13556 P13612 P14377 P14378	2	4	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11711 C11717 C11718 C11767 C11853 C11865 C11867 C11903 C11906 C11966 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C15450	P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P15450	2	5	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C15474 C15489	P15474 P15489	2	6	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C15788	P15788	4	2	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C11529 C15777 C15796	P11529 P15777 P15796	4	5	2
Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen	Injection	Hyrimoz	SZ	MP	C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 C15764 C15765 C15795	P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 P15764 P15765 P15795	6	0	2

[3] Schedule 1, Part 1, entries for Atorvastatin in the form Tablet 10 mg (as calcium)

omit:

Atorvastatin	Tablet 10 mg (as calcium)	Oral	NOUMED ATORVASTATIN	VO	MP NP		30	5	30
Atorvastatin	Tablet 10 mg (as calcium)	Oral	NOUMED ATORVASTATIN	VO	MP NP	P14238	60	5	30

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

omit:

Atorvastatin	Tablet 20 mg (as calcium)	Oral	NOUMED ATORVASTATIN	VO	MP NP		30	5	30
Atorvastatin	Tablet 20 mg (as calcium)	Oral	NOUMED ATORVASTATIN	VO	MP NP	P14238	60	5	30

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

omit:

Atorvastatin	Tablet 40 mg (as calcium)	Oral	NOUMED ATORVASTATIN	VO	MP NP		30	5	30
Atorvastatin	Tablet 40 mg (as calcium)	Oral	NOUMED ATORVASTATIN	VO	MP NP	P14238	60	5	30

[6] Schedule 1, Part 1, entries for Atorvastatin in the form Tablet 80 mg (as calcium)

omit:

Atorvastatin	Tablet 80 mg (as calcium)	Oral	NOUMED ATORVASTATIN	VO	MP NP		30	5	30
Atorvastatin	Tablet 80 mg (as calcium)	Oral	NOUMED ATORVASTATIN	VO	MP NP	P14238	60	5	30

[7] Schedule 1, Part 1, entries for Bisoprolol in the form Tablet containing bisoprolol fumarate 2.5 mg

omit:

Bisoprolol	Tablet containing bisoprolol fumarate 2.5 mg	Oral	Cipla Bisoprolol	LR	MP NP	C5324	P5324	28	5	28	
Bisoprolol	Tablet containing bisoprolol fumarate 2.5 mg	Oral	Cipla Bisoprolol	LR	MP NP	C14251	P14251	56	5	28	

[8] Schedule 1, Part 1, entries for Bisoprolol in the form Tablet containing bisoprolol fumarate 5 mg

omit:

Bisoprolol	Tablet containing bisoprolol fumarate 5 mg	Oral	Cipla Bisoprolol	LR	MP NP	C5324	P5324	28	5	28	
Bisoprolol	Tablet containing bisoprolol fumarate 5 mg	Oral	Cipla Bisoprolol	LR	MP NP	C14251	P14251	56	5	28	

[9] Schedule 1, Part 1, entries for Bisoprolol in the form Tablet containing bisoprolol fumarate 10 mg

omit:

Bisoprolol	Tablet containing bisoprolol fumarate 10 mg	Oral	Cipla Bisoprolol	LR	MP NP	C5324	P5324	28	5	28	
Bisoprolol	Tablet containing bisoprolol fumarate 10 mg	Oral	Cipla Bisoprolol	LR	MP NP	C14251	P14251	56	5	28	

[10] Schedule 1, Part 1, entries for Bortezomib in the form Powder for injection 1 mg

omit:

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

[11] Schedule 1, Part 1, entries for Bortezomib in the form Powder for injection 2.5 mg

omit:

Bortezomib	Powder for injection 2.5 mg	Injection	DBL Bortezomib	PF	MP	C11099 C13745	See Note 3	See Note 3	1	D(100)

[12] Schedule 1, Part 1, entries for Celecoxib in the form Capsule 100 mg

omit:

Celecoxib	Capsule 100 mg	Oral	NOUMED CELECOXIB	VO	MP NP	C4907 C4962	60	3	60

[13] Schedule 1, Part 1, entries for Celecoxib in the form Capsule 200 mg

omit:

Celecoxib	Capsule 200 mg	Oral	NOUMED CELECOXIB	VO	MP NP	C4907 C4962	30	3	30

[14] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg *[Brand: Dasatinib ARX; Maximum Quantity: 60; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[15] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg *[Brand: Dasatinib Dr.Reddy's; Maximum Quantity: 60; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[16] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg *[Brand: Dasatinib Sandoz; Maximum Quantity: 60; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[17] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg *[Brand: Dasatinib SUN; Maximum Quantity: 60; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[18] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg *[Brand: DASATINIB-TEVA; Maximum Quantity: 60; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[19] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg *[Brand: Dasatinib Viatris; Maximum Quantity: 60; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[20] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg *[Brand: Sprycel; Maximum Quantity: 60; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[21] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg *[Brand: Dasatinib ARX; Maximum Quantity: 60; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[22] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg *[Brand: Dasatinib Dr.Reddy's; Maximum Quantity: 60; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) *insert in numerical order in the column headed "Circumstances":* C16228 C16229 C16252

(c) *omit from the column headed "Purposes":* P9367 P9468 P9469

(d) *insert in numerical order in the column headed "Purposes":* P16228 P16229 P16252

[23] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg *[Brand: Dasatinib Sandoz; Maximum Quantity: 60; Number of Repeats: 2]*

(a) *omit from the column headed "Circumstances":* C9367 C9468 C9469

(b) *insert in numerical order in the column headed "Circumstances":* C16228 C16229 C16252

(c) *omit from the column headed "Purposes":* P9367 P9468 P9469

(d) *insert in numerical order in the column headed "Purposes":* P16228 P16229 P16252

[24] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg *[Brand: Dasatinib SUN; Maximum Quantity: 60; Number of Repeats: 2]*

(a) *omit from the column headed "Circumstances":* C9367 C9468 C9469

(b) *insert in numerical order in the column headed "Circumstances":* C16228 C16229 C16252

(c) *omit from the column headed "Purposes":* P9367 P9468 P9469

(d) *insert in numerical order in the column headed "Purposes":* P16228 P16229 P16252

[25] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg *[Brand: DASATINIB-TEVA; Maximum Quantity: 60; Number of Repeats: 2]*

(a) *omit from the column headed "Circumstances":* C9367 C9468 C9469

(b) *insert in numerical order in the column headed "Circumstances":* C16228 C16229 C16252

(c) *omit from the column headed "Purposes":* P9367 P9468 P9469

(d) *insert in numerical order in the column headed "Purposes":* P16228 P16229 P16252

[26] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg *[Brand: Dasatinib Viatris; Maximum Quantity: 60; Number of Repeats: 2]*

(a) *omit from the column headed "Circumstances":* C9367 C9468 C9469

(b) *insert in numerical order in the column headed "Circumstances":* C16228 C16229 C16252

(c) *omit from the column headed "Purposes":* P9367 P9468 P9469

(d) *insert in numerical order in the column headed "Purposes":* P16228 P16229 P16252

[27] **Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg *[Brand: Sprycel; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9367 C9468 C9469

(b) *insert in numerical order in the column headed "Circumstances":* C16228 C16229 C16252

(c) *omit from the column headed "Purposes":* P9367 P9468 P9469

(d) *insert in numerical order in the column headed "Purposes":* P16228 P16229 P16252

[28] **Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg *[Brand: Dasatinib ARX; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9367 C9468 C9469

(b) *insert in numerical order in the column headed "Circumstances":* C16228 C16229 C16252

(c) *omit from the column headed "Purposes":* P9367 P9468 P9469

(d) *insert in numerical order in the column headed "Purposes":* P16228 P16229 P16252

[29] **Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg *[Brand: Dasatinib Dr.Reddy's; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9367 C9468 C9469

(b) *insert in numerical order in the column headed "Circumstances":* C16228 C16229 C16252

(c) *omit from the column headed "Purposes":* P9367 P9468 P9469

(d) *insert in numerical order in the column headed "Purposes":* P16228 P16229 P16252

[30] **Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg *[Brand: Dasatinib Sandoz; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9367 C9468 C9469

(b) *insert in numerical order in the column headed "Circumstances":* C16228 C16229 C16252

(c) *omit from the column headed "Purposes":* P9367 P9468 P9469

(d) *insert in numerical order in the column headed "Purposes":* P16228 P16229 P16252

[31] **Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg *[Brand: Dasatinib SUN; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9367 C9468 C9469

(b) *insert in numerical order in the column headed "Circumstances":* C16228 C16229 C16252

(c) *omit from the column headed "Purposes":* P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[32] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg *[Brand: DASATINIB-TEVA; Maximum Quantity: 60; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[33] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg *[Brand: Dasatinib Viatris; Maximum Quantity: 60; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[34] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg *[Brand: Sprycel; Maximum Quantity: 60; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[35] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg *[Brand: Dasatinib ARX; Maximum Quantity: 30; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[36] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg *[Brand: Dasatinib Dr.Reddy's; Maximum Quantity: 30; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[37] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg *[Brand: Dasatinib Sandoz; Maximum Quantity: 30; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[38] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg *[Brand: Dasatinib SUN; Maximum Quantity: 30; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[39] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg *[Brand: DASATINIB-TEVA; Maximum Quantity: 30; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[40] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg *[Brand: Dasatinib Viatris; Maximum Quantity: 30; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[41] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg *[Brand: Sprycel; Maximum Quantity: 30; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C9367 C9468 C9469

(b) insert in numerical order in the column headed "Circumstances": C16228 C16229 C16252

(c) omit from the column headed "Purposes": P9367 P9468 P9469

(d) insert in numerical order in the column headed "Purposes": P16228 P16229 P16252

[42] Schedule 1, Part 1, entries for Dimethyl fumarate in the form Capsule (modified release) 120 mg

omit:

Dimethyl fumarate	Capsule (modified release) 120 mg	Oral	Dimethyl Fumarate MSN	LR	MP	C10139 C10140	28	0	14

[43] Schedule 1, Part 1, entries for Dimethyl fumarate in the form Capsule (modified release) 240 mg

omit:

Dimethyl fumarate	Capsule (modified release) 240 mg	Oral	Dimethyl Fumarate MSN	LR	MP	C10139	56	5	56

[44] Schedule 1, Part 1, entries for Duloxetine in the form Capsule 30 mg (as hydrochloride)

omit:

Duloxetine	Capsule 30 mg (as hydrochloride)	Oral	Cymbalta	LY	MP NP	C5650	28	0	28

[45] Schedule 1, Part 1, entries for Duloxetine in the form Capsule 60 mg (as hydrochloride)

omit:

Duloxetine	Capsule 60 mg (as hydrochloride)	Oral	Cymbalta	LY	MP NP	C5650	28	5	28

[46] Schedule 1, Part 1, entry for Enzalutamide *[Maximum Quantity: 112; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C12937 *substitute:* C16233

(b) omit from the column headed "Purposes": P12937 *substitute:* P16233

[47] Schedule 1, Part 1, after entry for Erlotinib in the form Tablet 150 mg (as hydrochloride) *[Brand: Erlotinib APOTEX]*

insert:

Erlotinib	Tablet 150 mg (as hydrochloride)	Oral	ERLOTINIB ARX	XT	MP	C4473 C4600 C7446		30	3	30

[48] Schedule 1, Part 1, entries for Escitalopram in the form Tablet 10 mg (as oxalate)

omit:

Escitalopram	Tablet 10 mg (as oxalate)	Oral	NOUMED ESCITALOPRAM	VO	MP NP	C4690 C4703 C4755 C4756 C4757	P4690 P4703 P4755 P4756 P4757	28	5	28
Escitalopram	Tablet 10 mg (as oxalate)	Oral	NOUMED ESCITALOPRAM	VO	MP NP	C15550 C15551 C15666 C15669 C15696	P15550 P15551 P15666 P15669 P15696	56	2	28

[49] Schedule 1, Part 1, entries for Escitalopram in the form Tablet 20 mg (as oxalate)

omit:

Escitalopram	Tablet 20 mg (as oxalate)	Oral	NOUMED ESCITALOPRAM	VO	MP NP	C4690 C4703 C4755 C4756 C4757	P4690 P4703 P4755 P4756 P4757	28	5	28
Escitalopram	Tablet 20 mg (as oxalate)	Oral	NOUMED ESCITALOPRAM	VO	MP NP	C15550 C15551 C15666 C15669 C15696	P15550 P15551 P15666 P15669 P15696	56	2	28

[50] Schedule 1, Part 1, entries for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)

(a) omit:

Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	Oral	Esomeprazole Mylan	AL	MP NP	C8774 C8775	P8774 P8775	30	1	30
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	Oral	Esomeprazole Mylan	AL	MP NP	C8776 C8780 C8827	P8776 P8780 P8827	30	5	30
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium	Oral	Esomeprazole	AL	MP	C11310	P11310	60	5	30

	trihydrate)		Mylan							
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	Oral	Esomeprazole Mylan	AL	MP NP	C15530 C15658 C15682	P15530 P15658 P15682	60	5	30
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	Oral	Esomeprazole Mylan	AL	MP	C15856	P15856	120	5	30

(b) omit from the column headed "Form" (all instances): Tablet (enteric coated) 20 mg (as magnesium trihydrate)

substitute (all instances): Tablet (enteric coated) 20 mg (as magnesium)

[51] Schedule 1, Part 1, entries for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)

(a) omit:

Esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	Oral	Esomeprazole Mylan	AL	MP NP	C8902	P8902	30	1	30
Esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	Oral	Esomeprazole Mylan	AL	MP NP	C8777 C8778	P8777 P8778	30	5	30
Esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	Oral	Esomeprazole Mylan	AL	MP	C11370	P11370	60	5	30
Esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	Oral	Esomeprazole Mylan	AL	MP NP	C15655 C15704	P15655 P15704	60	5	30
Esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	Oral	Esomeprazole Mylan	AL	MP	C15936	P15936	120	5	30

(b) omit from the column headed "Form" (all instances): Tablet (enteric coated) 40 mg (as magnesium trihydrate)

substitute (all instances): Tablet (enteric coated) 40 mg (as magnesium)

[52] Schedule 1, Part 1, entry for Famciclovir in the form Tablet 500 mg *[Brand: Ezovir]*

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

[53] Schedule 1, Part 1, entries for Fingolimod in the form Capsule 500 micrograms (as hydrochloride)

omit:

Fingolimod	Capsule 500 micrograms (as hydrochloride)	Oral	FINGOLIS	LR	MP	C10162 C10172		28	5	28

[54] Schedule 1, Part 1, entries for Fluoxetine in the form Capsule 20 mg (as hydrochloride)

omit:

Fluoxetine	Capsule 20 mg (as hydrochloride)	Oral	NOUMED FLUOXETINE	VO	MP NP	C4755 C6277	P4755 P6277	28	5	28
Fluoxetine	Capsule 20 mg (as hydrochloride)	Oral	NOUMED FLUOXETINE	VO	MP NP	C15582 C15666	P15582 P15666	56	2	28
Fluoxetine	Capsule 20 mg (as hydrochloride)	Oral	Prozac 20	LY	MP NP	C4755 C6277	P4755 P6277	28	5	28
Fluoxetine	Capsule 20 mg (as hydrochloride)	Oral	Prozac 20	LY	MP NP	C15582 C15666	P15582 P15666	56	2	28

[55] Schedule 1, Part 1, entries for Hypromellose in the form Eye drops 3 mg per mL, 10 mL

omit:

Hypromellose	Eye drops 3 mg per mL, 10 mL	Application to the eye	Genteal	AQ	MP NP AO	C15560	P15560	1	5	1
Hypromellose	Eye drops 3 mg per mL, 10 mL	Application to the eye	Genteal	AQ	MP NP AO	C15556	P15556	2	5	1
Hypromellose	Eye drops 3 mg per mL, 10 mL	Application to the eye	In a Wink Moisturising	IQ	MP NP AO	C15560	P15560	1	5	1
Hypromellose	Eye drops 3 mg per mL, 10 mL	Application to the eye	In a Wink Moisturising	IQ	MP NP AO	C15556	P15556	2	5	1

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

[57] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) *[Brand: ARX-IMATINIB; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[58] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) *[Brand: Imatinib-APOTEX; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[59] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) *[Brand: IMATINIB-DRLA; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[60] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) *[Brand: ARX-IMATINIB; Maximum Quantity: 30; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[61] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) *[Brand: Imatinib GH; Maximum Quantity: 30; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[62] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) *[Brand: Imatinib-APOTEX; Maximum Quantity: 30; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[63] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) *[Brand: IMATINIB-DRLA; Maximum Quantity: 30; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[64] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate) *[Brand: Gilmat; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[65] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate)** ***[Brand: Glivec; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[66] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate)** ***[Brand: Imanib; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[67] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate)** ***[Brand: IMATINIB RBX; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[68] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate)** ***[Brand: Imatinib Sandoz; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[69] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate)** ***[Brand: Imatinib-Teva; Maximum Quantity: 60; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[70] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate)** ***[Brand: Gilmat; Maximum Quantity: 30; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[71] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate)** ***[Brand: Glivec; Maximum Quantity: 30; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[72] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate)** ***[Brand: Imanib; Maximum Quantity: 30; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[73] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate)** ***[Brand: IMATINIB RBX; Maximum Quantity: 30; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[74] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate)** ***[Brand: Imatinib Sandoz; Maximum Quantity: 30; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[75] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate)** ***[Brand: Imatinib-Teva; Maximum Quantity: 30; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

[76] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 600 mg (as mesilate)** ***[Maximum Quantity: 30; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* C9203 C9207

(b) *insert in numerical order in the column headed "Circumstances":* C16238 C16249

(c) *omit from the column headed "Purposes":* P9203 P9207

(d) *insert in numerical order in the column headed "Purposes":* P16238 P16249

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

insert in the column headed "Purposes": P6214

[78] Schedule 1, Part 1, entry for Ketoprofen *[Maximum Quantity: 28; Number of Repeats: 3]*

insert in the column headed "Purposes": P6214

[79] Schedule 1, Part 1, entries for Lamotrigine in the form Tablet 25 mg

omit:

Lamotrigine	Tablet 25 mg	Oral	NOUMED LAMOTRIGINE	VO	MP NP	C11081	P11081	56	5	56
Lamotrigine	Tablet 25 mg	Oral	NOUMED LAMOTRIGINE	VO	MP NP	C14855	P14855	112	5	56

[80] Schedule 1, Part 1, entries for Lamotrigine in the form Tablet 50 mg

omit:

Lamotrigine	Tablet 50 mg	Oral	NOUMED LAMOTRIGINE	VO	MP NP	C11081	P11081	56	5	56
Lamotrigine	Tablet 50 mg	Oral	NOUMED LAMOTRIGINE	VO	MP NP	C14855	P14855	112	5	56

[81] Schedule 1, Part 1, entries for Lamotrigine in the form Tablet 100 mg

omit:

Lamotrigine	Tablet 100 mg	Oral	NOUMED LAMOTRIGINE	VO	MP NP	C11081	P11081	56	5	56
Lamotrigine	Tablet 100 mg	Oral	NOUMED LAMOTRIGINE	VO	MP NP	C14855	P14855	112	5	56

[82] Schedule 1, Part 1, entries for Lamotrigine in the form Tablet 200 mg

omit:

Lamotrigine	Tablet 200 mg	Oral	NOUMED LAMOTRIGINE	VO	MP NP	C11081	P11081	56	5	56
Lamotrigine	Tablet 200 mg	Oral	NOUMED LAMOTRIGINE	VO	MP NP	C14855	P14855	112	5	56

[83] Schedule 1, Part 1, entries for Lansoprazole in the form Capsule 30 mg

omit:

Lansoprazole	Capsule 30 mg	Oral	NOUMED LANSOPRAZOLE	VO	MP NP	C8774 C8775	P8774 P8775	28	1	28
Lansoprazole	Capsule 30 mg	Oral	NOUMED LANSOPRAZOLE	VO	MP NP	C8776 C8780	P8776 P8780	28	5	28
Lansoprazole	Capsule 30 mg	Oral	NOUMED LANSOPRAZOLE	VO	MP NP	C11310 C15530 C15658	P11310 P15530 P15658	56	5	28
Lansoprazole	Capsule 30 mg	Oral	NOUMED LANSOPRAZOLE	VO	MP	C15856	P15856	112	5	28

[84] Schedule 1, Part 1, entry for Liothyronine *[Maximum Quantity: 200; Number of Repeats: 2]*

(a) omit from the column headed "Circumstances": C15038

(b) omit from the column headed "Purposes": P15038

[85] Schedule 1, Part 1, entries for Metformin in the form Tablet containing metformin hydrochloride 500 mg *[Brand: APX-Metformin]*

omit from the column headed "Brand": APX-Metformin *substitute:* APX-METFORMIN

[86] Schedule 1, Part 1, entries for Metformin in the form Tablet containing metformin hydrochloride 850 mg *[Brand: APX-Metformin]*

omit from the column headed "Brand": APX-Metformin *substitute:* APX-METFORMIN

[87] Schedule 1, Part 1, entries for Metformin in the form Tablet containing metformin hydrochloride 1 g *[Brand: APX-Metformin]*

omit from the column headed "Brand": APX-Metformin *substitute:* APX-METFORMIN

[88] Schedule 1, Part 1, entries for Metoprolol in the form Tablet containing metoprolol tartrate 50 mg

omit:

Metoprolol	Tablet containing metoprolol tartrate 50 mg	Oral	NOUMED METOPROLOL	VO	MP NP			100	5	100
Metoprolol	Tablet containing metoprolol tartrate 50 mg	Oral	NOUMED METOPROLOL	VO	MP NP		P14238	200	5	100

[89] Schedule 1, Part 1, entries for Metoprolol in the form Tablet containing metoprolol tartrate 100 mg

omit:

Metoprolol	Tablet containing metoprolol tartrate 100 mg	Oral	NOUMED METOPROLOL	VO	MP NP		60	5	60
Metoprolol	Tablet containing metoprolol tartrate 100 mg	Oral	NOUMED METOPROLOL	VO	MP NP	P14238	120	5	60

[90] Schedule 1, Part 1, entries for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg

omit:

Mycophenolic acid	Capsule containing mycophenolate mofetil 250 mg	Oral	Ceptolate	AF	MP		300	5	50
Mycophenolic acid	Capsule containing mycophenolate mofetil 250 mg	Oral	Ceptolate	AF	MP	P14238	600	5	50

[91] Schedule 1, Part 1, entries for Nivolumab

insert in the column headed "Variations" (all instances): V15527

[92] Schedule 1, Part 1, entries for Nortriptyline in the form Tablet 10 mg (as hydrochloride)

omit:

Nortriptyline	Tablet 10 mg (as hydrochloride)	Oral	NortriTABS 10 mg	GH	MP NP	C6235 C6300	50	2	50

[93] Schedule 1, Part 1, entries for Nortriptyline in the form Tablet 25 mg (as hydrochloride)

omit:

Nortriptyline	Tablet 25 mg (as hydrochloride)	Oral	NortriTABS 25 mg	GH	MP NP	C6235 C6300	50	2	50

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

(a) omit from the column headed "Circumstances": C15370

(b) insert in numerical order in the column headed "Circumstances": C16234 C16240 C16241

(c) omit from the column headed "Purposes": P15370

(d) insert in numerical order in the column headed "Purposes": P16234 P16240 P16241

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

(a) omit from the column headed "Circumstances": C15370

(b) insert in numerical order in the column headed "Circumstances": C16234 C16240 C16241

(c) omit from the column headed "Purposes": P15370

(d) insert in numerical order in the column headed "Purposes": P16234 P16240 P16241

[96] Schedule 1, Part 1, entries for Paracetamol in the form Tablet 500 mg

omit:

Paracetamol	Tablet 500 mg	Oral	Parapane	AF	PDP	C5846	P5846	100	0	100
Paracetamol	Tablet 500 mg	Oral	Parapane	AF	MP NP	C5835	P5835	100	1	100
Paracetamol	Tablet 500 mg	Oral	Parapane	AF	PDP	C5885	P5885	300	0	100
Paracetamol	Tablet 500 mg	Oral	Parapane	AF	MP NP	C5865	P5865	300	4	100

[97] Schedule 1, Part 1, entry for Penicillamine in the form Tablet 125 mg *[Maximum Quantity: 200; Number of Repeats: 1]*

omit from the column headed "Purposes": P14238 *substitute:* P16078

[98] Schedule 1, Part 1, entry for Penicillamine in the form Tablet 250 mg *[Maximum Quantity: 200; Number of Repeats: 1]*

omit from the column headed "Purposes": P14238 *substitute:* P16078

[99] Schedule 1, Part 1, entries for Pregabalin in the form Capsule 25 mg

omit:

Pregabalin	Capsule 25 mg	Oral	NOUMED PREGABALIN	VO	MP NP	C4172		56	5	56

[100] Schedule 1, Part 1, entries for Pregabalin in the form Capsule 75 mg

omit:

Pregabalin	Capsule 75 mg	Oral	NOUMED PREGABALIN	VO	MP NP	C4172	56	5	56

[101] Schedule 1, Part 1, entries for Pregabalin in the form Capsule 150 mg

omit:

Pregabalin	Capsule 150 mg	Oral	NOUMED PREGABALIN	VO	MP NP	C4172	56	5	56

[102] Schedule 1, Part 1, entries for Pregabalin in the form Capsule 300 mg

omit:

Pregabalin	Capsule 300 mg	Oral	NOUMED PREGABALIN	VO	MP NP	C4172	56	5	56

[103] 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:

Risperidone	I.M. injection (modified release), set containing 1 pre-filled syringe powder for injection 75 mg and 1 pre-filled syringe diluent 383 microlitres	Injection	Risvan	SE	MP NP	C16231	1	5	1
Risperidone	I.M. injection (modified release), set containing 1 pre-filled syringe powder for injection 100 mg and 1 pre-filled syringe diluent 490 microlitres	Injection	Risvan	SE	MP NP	C16231	1	5	1

[104] Schedule 1, Part 1, entries for Safinamide

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

[105] Schedule 1, Part 1, entries for Sertraline in the form Tablet 50 mg (as hydrochloride)

omit:

Sertraline	Tablet 50 mg (as hydrochloride)	Oral	NOUMED SERTRALINE	VO	MP NP	C4755 C6277 C6289	P4755 P6277 P6289	30	5	30
Sertraline	Tablet 50 mg (as hydrochloride)	Oral	NOUMED SERTRALINE	VO	MP NP	C15582 C15583 C15666	P15582 P15583 P15666	60	2	30

[106] Schedule 1, Part 1, entries for Sertraline in the form Tablet 100 mg (as hydrochloride)

omit:

Sertraline	Tablet 100 mg (as hydrochloride)	Oral	NOUMED SERTRALINE	VO	MP NP	C4755 C6277 C6289	P4755 P6277 P6289	30	5	30
Sertraline	Tablet 100 mg (as hydrochloride)	Oral	NOUMED SERTRALINE	VO	MP NP	C15582 C15583 C15666	P15582 P15583 P15666	60	2	30

[107] Schedule 1, Part 1, entries for Simvastatin in the form Tablet 10 mg

omit:

Simvastatin	Tablet 10 mg	Oral	NOUMED SIMVASTATIN	VO	MP NP			30	5	30
Simvastatin	Tablet 10 mg	Oral	NOUMED SIMVASTATIN	VO	MP NP		P14238	60	5	30

[108] Schedule 1, Part 1, entries for Simvastatin in the form Tablet 20 mg

omit:

Simvastatin	Tablet 20 mg	Oral	NOUMED SIMVASTATIN	VO	MP NP			30	5	30
Simvastatin	Tablet 20 mg	Oral	NOUMED SIMVASTATIN	VO	MP NP		P14238	60	5	30

[109] Schedule 1, Part 1, entries for Simvastatin in the form Tablet 40 mg

omit:

Simvastatin	Tablet 40 mg	Oral	NOUMED SIMVASTATIN	VO	MP NP			30	5	30
Simvastatin	Tablet 40 mg	Oral	NOUMED	VO	MP		P14238	60	5	30

			SIMVASTATIN		NP					

[110] Schedule 1, Part 1, after entry for Sitagliptin with metformin in the form Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride *[Brand: Sitagliptin/Metformin Sandoz; Maximum Quantity: 112; Number of Repeats: 5]*

insert:

Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	SITAGLO-MET	CR	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride	Oral	SITAGLO-MET	CR	MP NP	C15288	P15288	112	5	56

[111] Schedule 1, Part 1, after entry for Sitagliptin with metformin in the form Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride *[Brand: Sitagliptin/Metformin Sandoz; Maximum Quantity: 112; Number of Repeats: 5]*

insert:

Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride	Oral	SITAGLO-MET	CR	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride	Oral	SITAGLO-MET	CR	MP NP	C15288	P15288	112	5	56

[112] Schedule 1, Part 1, after entry for Sitagliptin with metformin in the form Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride *[Brand: Sitagliptin/Metformin Sandoz; Maximum Quantity: 112; Number of Repeats: 5]*

insert:

Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride	Oral	SITAGLO-MET	CR	MP NP	C15276	P15276	56	5	56
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride	Oral	SITAGLO-MET	CR	MP NP	C15288	P15288	112	5	56

[113] Schedule 1, Part 1, entries for Somatropin in the form Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative)

substitute:

Somatropin	Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative)	Injection	Genotropin GoQuick	PF	MP	C12703 C12704 C12705 C12711 C12712 C12722 C12723 C12725 C12726 C12731 C12738 C12758 C12760 C12765 C12768 C12769 C12770 C12771 C12774 C12775 C12779 C12780 C12784 C12785 C12791 C12793 C12798 C12803 C12812 C12829 C12831 C12832 C12834 C12858 C12860 C12866 C12867 C12869 C12884 C12887 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13359 C13360 C13363 C13364 C14366 C16226 C16242 C16243	See Note 3	See Note 3	1	D(100)

[114] Schedule 1, Part 1, entries for Somatropin in the form Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative)

substitute:

Somatropin	Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative)	Injection	Genotropin GoQuick	PF	MP	C12703 C12704 C12705 C12711 C12712 C12722 C12723 C12725 C12726 C12731 C12738 C12758 C12760 C12765	See Note 3	See Note 3	1	D(100)

						C12768 C12769 C12770 C12771 C12774 C12775 C12779 C12780 C12784 C12785 C12791 C12793 C12798 C12803 C12812 C12829 C12831 C12832 C12834 C12858 C12860 C12866 C12867 C12869 C12884 C12887 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13359 C13360 C13363 C13364 C14366 C16226 C16242 C16243				

[115] Schedule 1, Part 1, entries for Somatropin in the form Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen

substitute:

Somatropin	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen	Injection	Norditropin FlexPro	NO	MP	C12703 C12704 C12711 C12712 C12722 C12723 C12725 C12726 C12731 C12738 C12758 C12760 C12765 C12769 C12770 C12771 C12774 C12775 C12779 C12780 C12784 C12785 C12798 C12803 C12812 C12829 C12831 C12832 C12834 C12858 C12860 C12866 C12867 C12884	See Note 3	See Note 3	1	D(100)

						C12929 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13359 C13360 C13363 C13364 C14366 C16226 C16242 C16243					

[116] Schedule 1, Part 1, entries for Somatropin in the form Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative)

substitute:

Somatropin	Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative)	Injection	Saizen	SG	MP	C12703 C12704 C12711 C12712 C12721 C12722 C12723 C12725 C12726 C12731 C12738 C12749 C12752 C12758 C12760 C12765 C12769 C12770 C12771 C12774 C12775 C12779 C12780 C12784 C12785 C12803 C12806 C12831 C12832 C12834 C12858 C12860 C12861 C12866 C12884 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13359 C13360 C13363 C13364 C14366 C16226 C16242 C16243	See Note 3	See Note 3	1	D(100)

[117] Schedule 1, Part 1, entries for Somatropin in the form Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative)

substitute:

Somatropin	Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative)	Injection	Saizen	SG	MP	C12703 C12704 C12711 C12712 C12721 C12722 C12723 C12725 C12726 C12731 C12738 C12749 C12752 C12758 C12760 C12765 C12769 C12770 C12771 C12774 C12775 C12779 C12780 C12784 C12785 C12803 C12806 C12831 C12832 C12834 C12858 C12860 C12861 C12866 C12884 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13359 C13360 C13363 C13364 C14366 C16226 C16242 C16243	See Note 3	See Note 3	1	D(100)

[118] Schedule 1, Part 1, entries for Sunitinib in the form Capsule 12.5 mg

omit:

Sunitinib	Capsule 12.5 mg	Oral	Sunitinib MSN	LR	MP	C11878 C13152 C13153	28	1	28
Sunitinib	Capsule 12.5 mg	Oral	Sunitinib MSN	LR	MP	C4862	28	2	28
Sunitinib	Capsule 12.5 mg	Oral	Sunitinib MSN	LR	MP	C11875	28	3	28
Sunitinib	Capsule 12.5 mg	Oral	Sunitinib MSN	LR	MP	C7471	28	5	28

[119] Schedule 1, Part 1, entries for Sunitinib in the form Capsule 25 mg

omit:

Sunitinib	Capsule 25 mg	Oral	Sunitinib MSN	LR	MP	C11878 C13152 C13153	28	1	28
Sunitinib	Capsule 25 mg	Oral	Sunitinib MSN	LR	MP	C4862	28	2	28
Sunitinib	Capsule 25 mg	Oral	Sunitinib MSN	LR	MP	C11875	28	3	28
Sunitinib	Capsule 25 mg	Oral	Sunitinib MSN	LR	MP	C7471	28	5	28

[120] Schedule 1, Part 1, entries for Sunitinib in the form Capsule 37.5 mg

omit:

Sunitinib	Capsule 37.5 mg	Oral	Sunitinib MSN	LR	MP	C11878 C13152 C13153	28	1	28
Sunitinib	Capsule 37.5 mg	Oral	Sunitinib MSN	LR	MP	C4862	28	2	28
Sunitinib	Capsule 37.5 mg	Oral	Sunitinib MSN	LR	MP	C11875	28	3	28
Sunitinib	Capsule 37.5 mg	Oral	Sunitinib MSN	LR	MP	C7471	28	5	28

[121] Schedule 1, Part 1, entries for Sunitinib in the form Capsule 50 mg

omit:

Sunitinib	Capsule 50 mg	Oral	Sunitinib MSN	LR	MP	C11878 C13152 C13153	28	1	28
Sunitinib	Capsule 50 mg	Oral	Sunitinib MSN	LR	MP	C4862	28	2	28
Sunitinib	Capsule 50 mg	Oral	Sunitinib MSN	LR	MP	C11875	28	3	28
Sunitinib	Capsule 50 mg	Oral	Sunitinib MSN	LR	MP	C7471	28	5	28

[122] Schedule 1, Part 1, after entry for Tafamidis

insert:

Talazoparib	Capsule 100 micrograms (as tosilate)	Oral	Talzenna	PF	MP	C16224	30	5	30
Talazoparib	Capsule 250 micrograms (as tosilate)	Oral	Talzenna	PF	MP	C16224	30	5	30

Talazoparib	Capsule 350 micrograms (as tosilate)	Oral	Talzenna	PF	MP	C16224		30	5	30
Talazoparib	Capsule 500 micrograms (as tosilate)	Oral	Talzenna	PF	MP	C16224		30	5	30

[123] Schedule 1, Part 1, entries for Telmisartan in the form Tablet 80 mg

omit:

Telmisartan	Tablet 80 mg	Oral	NOUMED TELMISARTAN	VO	MP NP			28	5	28
Telmisartan	Tablet 80 mg	Oral	NOUMED TELMISARTAN	VO	MP NP		P14238	56	5	28

[124] Schedule 1, Part 1, entry for Tofacitinib in the form Oral solution 1 mg per mL, 240 mL *[Maximum Quantity: 1; Number of Repeats: 5]*

(a) omit from the column headed "Circumstances": C14647

(b) omit from the column headed "Purposes": P14647

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

(a) omit from the column headed "Circumstances": C14647

(b) omit from the column headed "Purposes": P14647

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

(a) omit from the column headed "Circumstances": C14802

(b) omit from the column headed "Purposes": P14802

[127] Schedule 1, Part 2, omit entry for Acalabrutinib

[128] Schedule 1, Part 2, after entry for Glucose indicator-urine

insert:

Hypromellose with carbomer 980	Ocular lubricating gel 3 mg-2 mg per g, 10 g	Application to the eye	Genteal gel	AQ	1
Hypromellose with carbomer 980	Ocular lubricating gel 3 mg-2 mg per g, 10 g	Application to	HPMC PAA	IQ	1

the eye

[129] Schedule 4, Part 1, omit entry for Circumstances Code "C9203"

[130] Schedule 4, Part 1, omit entry for Circumstances Code "C9207"

[131] Schedule 4, Part 1, omit entry for Circumstances Code "C9367"

[132] Schedule 4, Part 1, omit entry for Circumstances Code "C9468"

[133] Schedule 4, Part 1, omit entry for Circumstances Code "C9469"

[134] Schedule 4, Part 1, omit entry for Circumstances Code "C12588"

[135] Schedule 4, Part 1, omit entry for Circumstances Code "C12937"

[136] Schedule 4, Part 1, omit entry for Circumstances Code "C14390"

[137] Schedule 4, Part 1, omit entry for Circumstances Code "C14431"

[138] Schedule 4, Part 1, omit entry for Circumstances Code "C14647"

[139] Schedule 4, Part 1, omit entry for Circumstances Code "C14802"

[140] Schedule 4, Part 1, omit entry for Circumstances Code "C15038"

[141] Schedule 4, Part 1, omit entry for Circumstances Code "C15370"

[142] Schedule 4, Part 1, entry for Circumstances Code "C15560"

omit from the column headed "Listed Drug": Hypromellose with carbomer 980

[143] Schedule 4, Part 1, omit entry for Circumstances Code "C15640"

[144] Schedule 4, Part 1, entry for Circumstance Code "C16094"

omit entry for Circumstances Code "C16094" and substitute:

C16094	P16094	CN16094	Voriconazole	Serious fungal infections Treatment and maintenance therapy The condition must be caused by Scedosporium species; OR The condition must be caused by Fusarium species.	Compliance with Authority Required procedures

				Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner.	

[145] Schedule 4, Part 1, entry for Circumstances Code "C16189"

omit entry for Circumstances Code "C16189" and substitute:

C16189	P16189	CN16189	Methylphenidate	Attention deficit hyperactivity disorder Patient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events; AND Patient must require continuous coverage over 12 hours; AND The treatment must not exceed a maximum daily dose of 72 mg of PBS-subsidised treatment with this drug. Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive.	Compliance with Authority Required procedures

[146] Schedule 4, Part 1, after entry for Circumstances Code "C16223"

insert:

C16224	P16224	CN16224	Talazoparib	Castration resistant metastatic carcinoma of the prostate The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND Patient must not have received prior PBS-subsidised novel hormonal drug in any non-metastatic setting of prostate cancer prior to commencing treatment with this drug for this condition; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance score no higher than 1 prior to treatment initiation; AND Patient must be undergoing concurrent treatment with enzalutamide, unless an intolerance to enzalutamide requires either a: (i) temporary cessation, (ii) permanent discontinuation; AND The treatment must not be a PBS-subsidised benefit beyond disease progression.	Compliance with Authority Required procedures
C16226	P16226	CN16226	Somatropin	Severe growth hormone deficiency Initial treatment of late onset growth hormone deficiency Must be treated by an endocrinologist; AND	Compliance with Written Authority Required procedures

				Patient must have onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease diagnosed at chronological age of 18 years or older; or Patient must have onset of growth hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years; AND Patient must have a diagnostic insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre. or Patient must have a diagnostic arginine infusion test with maximum serum GH less than 0.4 micrograms per litre. or Patient must have a diagnostic glucagon provocation test with maximum serum GH less than 3 micrograms per litre. or Patient must have: (a) a chronological age of 18 years or older, (b) established hypothalamic-pituitary disease, (c) at least three documented pituitary hormone deficiencies, (d) an IGF-1 concentration lower than the sex- and age-specific lower limit of normal in a patient. The authority application must be in writing and must include: Details of the proposed prescription; AND A completed Severe Growth Hormone Deficiency supporting information form; AND If applicable, results of the growth hormone simulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender.	
C16228	P16228	CN16228	Dasatinib	Acute lymphoblastic leukaemia Maintenance of first complete remission Patient must have previously received PBS-subsidised treatment with this drug for this condition; or Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with imatinib as a first-line therapy for this condition; AND The condition must be expressing the Philadelphia chromosome; or The condition must have the transcript BCR-ABL; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND Patient must be undergoing treatment with this drug that is occurring within the first 24 months from the first administered dose. or Patient must be undergoing treatment with this drug that is occurring beyond the first 24 months from the first administered dose - the patient meets the conditions as outlined below.	Compliance with Authority Required procedures

				Conditions for PBS-subsidy beyond 24 months of treatment On the first occasion an authority application extends PBS-subsidy beyond 24 months, confirm that 1) The condition is expressing the Philadelphia chromosome, 2) Measurable residual disease (MRD) is present, 3) MRD has been confirmed in at least one of (i) marrow, (ii) peripheral blood, 4) MRD has been confirmed within the preceding 6 months of this authority application, 5) MRD has been ascertained by at least one of (i) a molecular method, (ii) flow cytometry, 6) Allogenic stem cell transplantation is considered by the prescriber to be unsuitable for the patient. For any subsequent authority application beyond the 24 month time mark, confirm that MRD has been detected within the preceding 12 months of this subsequent authority application. Where MRD has since become undetectable, confirm that PBS-subsidy has not exceeded a further 12 months duration from the date that MRD became undetectable.	
C16229	P16229	CN16229	Dasatinib	Acute lymphoblastic leukaemia Induction and Consolidation therapy Patient must be newly diagnosed; AND The condition must be expressing the Philadelphia chromosome; or The condition must have the transcript BCR-ABL; AND The treatment must be in combination with chemotherapy or corticosteroids; AND Patient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition. or Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition. The authority application must be made in writing and must include (a) details of the proposed prescription; and (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and (c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided).	Compliance with Written Authority Required procedures

C16231	P16231	CN16231	Risperidone	Schizophrenia For a patient switching from oral risperidone, the prescriber must determine the patient dosage of this drug based on the current dose of oral risperidone according to the dose transition table in the Therapeutic Goods Administration (TGA) approved Product Information.	Compliance with Authority Required procedures - Streamlined Authority Code 16231
C16233	P16233	CN16233	Enzalutamide	Castration resistant metastatic carcinoma of the prostate The treatment must not be used in combination with chemotherapy; AND Patient must have a WHO performance status of 2 or less; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication). or Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation. or Patient must have been receiving PBS-subsidised treatment with abiraterone or abiraterone plus methylprednisolone for castration resistant metastatic prostate cancer prior to being associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation.	Compliance with Authority Required procedures
C16234	P16234	CN16234	Olaparib	Metastatic breast cancer Initial treatment The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene variant; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND Patient must have received chemotherapy in the neoadjuvant, adjuvant or metastatic setting; AND Patient must not have received PBS-subsidised treatment with this drug in any earlier line of treatment for breast cancer; AND The condition must be triple negative breast cancer; or The condition must be hormone-receptor positive breast cancer and the patient has either: (i) progressive disease after receiving endocrine therapy, (ii) been considered inappropriate for endocrine therapy; AND	Compliance with Authority Required procedures

				The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication. Retain all pathology imaging and investigative test results in the patient's medical records. Do not submit copies of these as part of the authority application. Treatment with this drug for this condition is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under metastatic disease is no longer available).	
C16238	P16238	CN16238	Imatinib	Acute lymphoblastic leukaemia Induction and Consolidation therapy Patient must be newly diagnosed; AND The condition must be expressing the Philadelphia chromosome; or The condition must have the transcript BCR-ABL; AND The treatment must be in combination with chemotherapy or corticosteroids; AND Patient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition. or Patient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition. A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, 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
C16240	P16240	CN16240	Olaparib	Early breast cancer Initial treatment The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND Patient must have received neoadjuvant or adjuvant chemotherapy; AND The treatment must be adjuvant to surgical resection; AND The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene variant; AND Patient must have received neoadjuvant chemotherapy, and residual invasive cancer is confirmed in the breast and/or resected lymph nodes (pathological complete response was not achieved); or Patient must have received adjuvant chemotherapy for triple negative breast cancer, and has either: (a) node positive disease is present, (b) a primary tumour greater than 20 mm; or	Compliance with Authority Required procedures

				Patient must have received adjuvant chemotherapy for hormone receptor positive breast cancer, and has at least 4 positive lymph nodes; AND The treatment must not be a PBS-subsidised benefit beyond the following, whichever comes first: (i) a total of 52 weeks of treatment (including any non-PBS-subsidised supply), (ii) disease recurrence. Mark any remaining repeat prescriptions with the word 'cancelled' where (i)/ (ii) has occurred; AND The treatment must be commenced within 12 weeks of completing other therapy noting that other therapy can be any of the following therapy: (i) surgery, (ii) radiotherapy, (iii) chemotherapy; AND The treatment must not be in combination with any of the following: (i) abemaciclib, (ii) pembrolizumab. Retain all pathology imaging and investigative test results in the patient's medical records. Treatment with this drug for this condition is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under metastatic disease is no longer available).	
C16241	P16241	CN16241	Olaparib	Metastatic breast cancer Continuing treatment Patient must have received previous PBS-subsidised treatment with this drug in the metastatic setting; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition.	Compliance with Authority Required procedures
C16242	P16242	CN16242	Somatropin	Severe growth hormone deficiency Initial treatment of childhood onset growth hormone deficiency in a patient who has received PBS-subsidised treatment as a child Must be treated by an endocrinologist; AND Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition as a child; Patient must have a mature skeleton. Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency. The authority application must be in writing and must include:	Compliance with Written Authority Required procedures

				Details of the proposed prescription; AND A completed Severe Growth Hormone Deficiency supporting information form.	
C16243	P16243	CN16243	Somatropin	Severe growth hormone deficiency Initial treatment of childhood onset growth hormone deficiency in a patient who has received non-PBS subsidised treatment as a child Must be treated by an endocrinologist; AND Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; AND Patient must have previously received non-PBS subsidised treatment with this drug for this condition as a child; AND Patient must have current or historical evidence of an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; or Patient must have current or historical evidence of an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; or Patient must have current or historical evidence of a glucagon provocation test with maximum serum GH less than 3 micrograms per litre; Patient must have a mature skeleton. Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency. The authority application must be in writing and must include: Details of the proposed prescription; AND A completed Severe Growth Hormone Deficiency supporting information form; AND Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender.	Compliance with Written Authority Required procedures
C16249	P16249	CN16249	Imatinib	Acute lymphoblastic leukaemia Maintenance of first complete remission Patient must have previously received PBS-subsidised treatment with this drug for this condition; or Patient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; AND The condition must be expressing the Philadelphia chromosome; or The condition must have the transcript BCR-ABL; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16249

				Patient must be undergoing treatment with this drug that is occurring within the first 24 months from the first administered dose. or Patient must be undergoing treatment with this drug that is occurring beyond the first 24 months from the first administered dose - the patient meets the conditions as outlined below. Conditions for PBS-subsidy beyond 24 months of treatment On the first occasion an authority application extends PBS-subsidy beyond 24 months, by annotating the prescription with the Streamlined Authority Required code, the prescriber is declaring that 1) The condition is expressing the Philadelphia chromosome, 2) Measurable residual disease (MRD) is present, 3) MRD has been confirmed in at least one of (i) marrow, (ii) peripheral blood, 4) MRD has been confirmed within the preceding months of this authority application, 5) MRD has been ascertained by at least one of (i) a molecular method, (ii) flow cytometry, 6) Allogenic stem cell transplantation is considered by the prescriber to be unsuitable for the patient. For any subsequent authority application beyond the 24 month time mark, confirm that MRD has been detected within the preceding 12 months of this subsequent authority application. Where MRD has since become undetectable, confirm that PBS-subsidy has not exceeded a further 12 months duration from the date that MRD became undetectable.	
C16252	P16252	CN16252	Dasatinib	Acute lymphoblastic leukaemia Initial treatment The condition must be expressing the Philadelphia chromosome; or The condition must have the transcript BCR-ABL; AND Patient must have failed treatment with chemotherapy; AND Patient must have failed treatment with imatinib; AND Patient must have failed an allogeneic haemopoeitic stem cell transplantation if applicable. Failure of treatment is defined as either: (i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib; (ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib; (iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.	Compliance with Written Authority Required procedures

		Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission. The authority application must be made in writing and must include: (a) details of the proposed prescription; and (b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and (c) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided.

[147] Schedule 4, Part 2, second entry for Variation Code "V15457"

omit from the column headed "Variation Code": V15457 *substitute:* V15527

[148] Schedule 5, entry for Abacavir with lamivudine

omit from the column headed "Brand": Abacavir/Lamivudine Mylan

[149] Schedule 5, omit entries for Acalabrutinib

[150] Schedule 5, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen

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

[151] Schedule 5, entries for Atorvastatin

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

[152] Schedule 5, entries for Bisoprolol

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

[153] Schedule 5, entries for Celecoxib

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

[154] Schedule 5, entries for Dimethyl fumarate

omit from the column headed "Brand" (all instances): Dimethyl Fumarate MSN

[155] Schedule 5, entries for Duloxetine

substitute:

Duloxetine	GRP-19918	Capsule 30 mg (as hydrochloride)	Oral	APO-Duloxetine Duloxecor Duloxetine Sandoz Duloxetine Sandoz 30 DYTREX 30 Tixol 30
Duloxetine	GRP-19957	Capsule 60 mg (as hydrochloride)	Oral	APO-Duloxetine Duloxecor Duloxetine Sandoz Duloxetine Sandoz 60 DYTREX 60 Tixol 60

[156] Schedule 5, entry for Erlotinib in the form Tablet 150 mg (as hydrochloride)

insert in the column headed "Brand" after entry for the Brand "Erlotinib APOTEX": ERLOTINIB ARX

[157] Schedule 5, entries for Escitalopram

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

[158] Schedule 5, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)

(a) omit from the column headed "Form": Tablet (enteric coated) 40 mg (as magnesium trihydrate) *substitute:* Tablet (enteric coated) 40 mg (as magnesium)

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

[159] Schedule 5, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)

(a) omit from the column headed "Form": Tablet (enteric coated) 20 mg (as magnesium trihydrate) *substitute:* Tablet (enteric coated) 20 mg (as magnesium)

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

[160] Schedule 5, entry for Fingolimod

substitute:

Fingolimod	GRP-26766	Capsule 500 micrograms (as hydrochloride)	Oral	AKM Fingolimod Fingolimod Sandoz Fingolimod SUN Fingolimod-Teva

				Fynod Gilenya Pharmacor Fingolimod

[161] Schedule 5, entry for Fluoxetine

substitute:

Fluoxetine	GRP-24550	Capsule 20 mg (as hydrochloride)	Oral	APO-Fluoxetine Blooms the Chemist Fluoxetine FLUOTEX Fluoxetine APOTEX Fluoxetine generichealth Fluoxetine Sandoz Zactin

[162] Schedule 5, omit entry for Hypromellose

[163] Schedule 5, entries for Lamotrigine

substitute:

Lamotrigine	GRP-19640	Tablet 200 mg	Oral	APX-Lamotrigine Lamictal LAMITAN Lamotrigine GH LAMOTRIGINE-WGR Logem Reedos 200 Sandoz Lamotrigine
Lamotrigine	GRP-19706	Tablet 100 mg	Oral	APX-Lamotrigine Lamictal LAMITAN Lamotrigine GH LAMOTRIGINE-WGR Logem Reedos 100 Sandoz Lamotrigine
Lamotrigine	GRP-19758	Tablet 50 mg	Oral	APX-Lamotrigine Lamictal LAMITAN Lamotrigine GH LAMOTRIGINE-WGR

				Logem Reedos 50 Sandoz Lamotrigine
Lamotrigine	GRP-19807	Tablet 25 mg	Oral	APX-Lamotrigine Lamictal LAMITAN Lamotrigine GH LAMOTRIGINE-WGR Logem Reedos 25 Sandoz Lamotrigine

[164] Schedule 5, entry for Lansoprazole in the form Capsule 30 mg

omit from the column headed "Brand": NOUMED LANSOPRAZOLE

[165] Schedule 5, entry for Metformin in each of the forms: Tablet containing metformin hydrochloride 850 mg; Tablet containing metformin hydrochloride 500 mg; and Tablet containing metformin hydrochloride 1g

omit from the column headed "Brand": APX-Metformin *substitute:* APX-METFORMIN

[166] Schedule 5, entries for Metoprolol

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

[167] Schedule 5, entry for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg

omit from the column headed "Brand": Ceptolate

[168] Schedule 5, omit entries for Nortriptyline

[169] Schedule 5, entries for Ondansetron

substitute:

Ondansetron	GRP-15983	Tablet (orally disintegrating) 4 mg	Oral	APX-Ondansetron ODT Ondansetron Mylan ODT Ondansetron ODT-DRLA Ondansetron ODT Lupin Ondansetron ODT Viatris ONDANSETRON ODT-WGR Ondansetron SZ ODT Zotren ODT

Ondansetron	GRP-15983	Wafer 4 mg	Oral	Zofran Zydis
Ondansetron	GRP-15402	Tablet (orally disintegrating) 8 mg	Oral	APX-Ondansetron ODT Ondansetron Mylan ODT Ondansetron ODT-DRLA Ondansetron ODT Lupin Ondansetron ODT Viatris ONDANSETRON ODT-WGR Ondansetron SZ ODT Zotren ODT
Ondansetron	GRP-15402	Wafer 8 mg	Oral	Zofran Zydis
Ondansetron	GRP-19791	Tablet 4 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron APX-Ondansetron Ondansetron-DRLA Ondansetron Mylan Tablets Ondansetron SZ Ondansetron Tablets Viatris ONDANSETRON-WGR Zofran Zotren 4
Ondansetron	GRP-19626	Tablet 8 mg (as hydrochloride dihydrate)	Oral	APO-Ondansetron APX-Ondansetron Ondansetron-DRLA Ondansetron Mylan Tablets Ondansetron SZ Ondansetron Tablets Viatris ONDANSETRON-WGR Zofran Zotren 8

[170] Schedule 5, entry for Paracetamol in the form Tablet 500 mg

omit from the column headed "Brand": Parapane

[171] Schedule 5, entry for Pioglitazone in the form Tablet 15 mg (as hydrochloride) *[GRP-19814]*

substitute:

Pioglitazone	GRP-19814	Tablet 15 mg (as hydrochloride)	Oral	Actos APOTEX-Pioglitazone ARX-PIOGLITAZONE Vexazone

[172] Schedule 5, entry for Pioglitazone in the form Tablet 30 mg (as hydrochloride) *[GRP-19943]*

substitute:

Pioglitazone	GRP-19943	Tablet 30 mg (as hydrochloride)	Oral	Actos APOTEX-Pioglitazone ARX-PIOGLITAZONE Vexazone

[173] Schedule 5, entries for Pregabalin

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

[174] Schedule 5, omit entry for Quinapril in the form Tablet 20 mg (as hydrochloride)

[175] Schedule 5, omit entry for Quinapril in the form Tablet 10 mg (as hydrochloride)

[176] Schedule 5, entries for Sertraline

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

[177] Schedule 5, entry for Simvastatin in each of the forms: Tablet 20 mg; Tablet 40 mg; and Tablet 10 mg

omit from the column headed "Brand": NOUMED SIMVASTATIN

[178] Schedule 5, entry for Sitagliptin with metformin in each of the forms: Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride; Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride; and Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride

insert in the column headed "Brand" after entry for the Brand "Sitagliptin/Metformin Sandoz": SITAGLO-MET

[179] Schedule 5, entries for Sunitinib

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

[180] Schedule 5, entry for Telmisartan in the form Tablet 80 mg

omit from the column headed "Brand": NOUMED TELMISARTAN