PB 84 of 2025

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

National Health Act 1953

I, REBECCA RICHARDSON, 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 28 July 2025

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

Authorised Version F2025L00877 registered 31/07/2025

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1. Name

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

(2) This Instrument may also be cited as PB 84 of 2025.

2. Commencement

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

Commencement Information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 August 2025	1 August 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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Schedule 1—Amendments

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

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

(a) omit from the column headed "Circumstances": C16771

(b) insert in numerical order in the column headed "Circumstances": C16932

[2] Schedule 1, Part 1, after entry for Abiraterone in the form Tablet containing abiraterone acetate 250 mg *[Brand: Abiraterone-Teva]*

insert:

Abiraterone	Tablet containing abiraterone acetate 250 mg	Oral	ZYRON	NB	MP	C13945	120	2	120

[3] Schedule 1, Part 1, after entry for Abiraterone in the form Tablet containing abiraterone acetate 500 mg *[Brand: Abiraterone-Teva]*

insert:

Abiraterone	Tablet containing abiraterone acetate 500 mg	Oral	ZYRON	NB	MP	C13945	60	2	60

[4] Schedule 1, Part 1, entries for Aciclovir in the form Tablet 800 mg

omit:

Aciclovir	Tablet 800 mg	Oral	Aciclovir APOTEX	TY	MP NP	C5959 C5967	35	0	35

[5] Schedule 1, Part 1, entry for Adalimumab in the form Injection 20 mg in 0.2 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed "Circumstances": C15450

(b) omit from the column headed "Purposes": P15450

[6] Schedule 1, Part 1, entry for Adalimumab in the form Injection 20 mg in 0.4 mL pre-filled syringe *[Brand: Abrilada; Maximum Quantity: 2; Number of Repeats: 5]*

(a) omit from the column headed "Circumstances": C15450

(b) omit from the column headed "Purposes": P15450

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[7] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 20 mg in 0.4 mL pre-filled syringe *[Brand: Amgevita; Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

[8] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Brand: Hadlima; Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

[9] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Brand: Humira; Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

[10] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Brand: Hyrimoz; Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

[11] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

[12] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Hadlima; Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

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[13] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Humira; Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

[14] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Hyrimoz; Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

[15] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Brand: Yuflyma; Maximum Quantity: 2; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

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

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

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

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

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

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

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

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

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

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

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

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

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

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

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

(a) *omit from the column headed "Circumstances":* C15450

(b) *omit from the column headed "Purposes":* P15450

[24] **Schedule 1, Part 1, entries for Afatinib**

omit:

Afatinib	Tablet 50 mg	Oral	Giotrif	BY	MP	C7613 C16404	28	3	28

[25] **Schedule 1, Part 1, entries for Amino acid formula with vitamins and minerals without lysine and low in tryptophan**

omit:

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Amino acid formula with vitamins and minerals without lysine and low in tryptophan	Sachets containing oral powder 24 g, 30 (GA gel)	Oral	GA gel	VF	MP NP	C5323 C11482	4	5	1	

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

omit:

Arsenic	Injection concentrate containing arsenic trioxide 10 mg in 10 mL	Injection	Arsenic Trioxide-AFT	AE	MP	C4793 C5997 C6018	See Note 3	See Note 3	10	D(100)

[27] Schedule 1, Part 1, omit entries for Betaxolol

[28] Schedule 1, Part 1, entries for Bortezomib in the form Powder for injection 3.5 mg

omit:

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

[29] Schedule 1, Part 1, entry for Cabozantinib in the form Tablet 20 mg *[Maximum Quantity: 30; Number of Repeats: 5]*

(a) omit from the column headed "Circumstances": C15518

(b) omit from the column headed "Purposes": P15518

[30] Schedule 1, Part 1, entry for Cabozantinib in the form Tablet 40 mg *[Maximum Quantity: 30; Number of Repeats: 5]*

(a) omit from the column headed "Circumstances": C15518

(b) omit from the column headed "Purposes": P15518

[31] Schedule 1, Part 1, entry for Cabozantinib in the form Tablet 60 mg *[Maximum Quantity: 30; Number of Repeats: 5]*

(a) omit from the column headed "Circumstances": C15518

(b) omit from the column headed "Purposes": P15518

[32] Schedule 1, Part 1, after entry for Dabigatran etexilate in the form Capsule 75 mg (as mesilate) *[Brand: ARX-Dabigatran]*

insert:

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Dabigatran etexilate	Capsule 75 mg (as mesilate)	Oral	Dabigatran Viatris	AF	MP NP	C4402		60	0	60

[33] Schedule 1, Part 1, after entry for Dabigatran etexilate in the form Capsule 110 mg (as mesilate) *[Brand: Dabigatran Sandoz; Maximum Quantity: 120; Number of Repeats: 5]*

insert:

Dabigatran etexilate	Capsule 110 mg (as mesilate)	Oral	Dabigatran Viatris	AF	MP NP	C4402	P4402	60	0	60
Dabigatran etexilate	Capsule 110 mg (as mesilate)	Oral	Dabigatran Viatris	AF	MP NP	C4269	P4269	60	5	60
Dabigatran etexilate	Capsule 110 mg (as mesilate)	Oral	Dabigatran Viatris	AF	MP NP	C14301	P14301	120	5	60

[34] Schedule 1, Part 1, after entry for Dabigatran etexilate in the form Capsule 150 mg (as mesilate) *[Brand: Dabigatran Sandoz; Maximum Quantity: 120; Number of Repeats: 5]*

insert:

Dabigatran etexilate	Capsule 150 mg (as mesilate)	Oral	Dabigatran Viatris	AF	MP NP	C4269	P4269	60	5	60
Dabigatran etexilate	Capsule 150 mg (as mesilate)	Oral	Dabigatran Viatris	AF	MP NP	C14301	P14301	120	5	60

[35] Schedule 1, Part 1, entries for Denosumab

insert as first entry:

Denosumab	Injection 60 mg in 1 mL pre-filled syringe	Injection	Jubbonti	SZ	MP NP	C6524 C6548	1	0	1

[36] Schedule 1, Part 1, after entry for Denosumab in the form Injection 60 mg in 1 mL pre-filled syringe *[Brand: Prolia]*

insert:

Denosumab	Injection 120 mg in 1.7 mL	Injection	Wyost	SZ	MP NP	C16512 C16514 C16608	1	5	1

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[37] Schedule 1, Part 1, after entry for Drospirenone *[Pack Quantity: 4]*

insert:

Drospirenone	Pack containing 24 tablets 4 mg and 4 inert tablets, 3	Oral	Slinda	HB	MP MW NP	1	3	1
Drospirenone with ethinylestradiol	Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets	Oral	Isabelle	GQ	MP MW NP	3	3	1
Drospirenone with ethinylestradiol	Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets	Oral	Isabelle	GQ	MP MW NP	3	3	3
Drospirenone with ethinylestradiol	Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets	Oral	Rosalee	SZ	MP MW NP	3	3	1
Drospirenone with ethinylestradiol	Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets	Oral	Rosalee	SZ	MP MW NP	3	3	3

[38] Schedule 1, Part 1, after entry for Drospirenone with ethinylestradiol in the form Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets *[Brand: Yasmin; Pack Quantity: 3]*

insert:

Drospirenone with ethinylestradiol	Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets	Oral	Yelena	XT	MP MW NP	3	3	1
Drospirenone with	Pack containing 21 tablets 3 mg drospirenone with	Oral	Yelena	XT	MP MW	3	3	3

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ethinylestradiol	30 micrograms ethinylestradiol and 7 inert tablets				NP				
Drospirenone with ethinylestradiol	Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets	Oral	Bella	GQ	MP MW NP	3	3	1	
Drospirenone with ethinylestradiol	Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets	Oral	Bella	GQ	MP MW NP	3	3	3	
Drospirenone with ethinylestradiol	Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets	Oral	Rosie	SZ	MP MW NP	3	3	1	
Drospirenone with ethinylestradiol	Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets	Oral	Rosie	SZ	MP MW NP	3	3	3	
Drospirenone with ethinylestradiol	Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets	Oral	YANA	XT	MP MW NP	3	3	1	
Drospirenone with ethinylestradiol	Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets	Oral	YANA	XT	MP MW NP	3	3	3	

[39] Schedule 1, Part 1, entries for Durvalumab in each of the forms: Solution concentrate for I.V. infusion 120 mg in 2.4 mL; and Solution concentrate for I.V. infusion 500 mg in 10 mL

insert in numerical order in the column headed "Circumstances": C16814 C16953

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

insert:

Eflornithine	Tablet 192 mg (as hydrochloride)	Oral	Ifinwil	NE	MP	See Note 3	See Note 3	See Note 3	See Note 3	100	D(100)

[41] Schedule 1, Part 1, after entry for Escitalopram in the form Tablet 10 mg (as oxalate) *[Brand: Escitalopram Sandoz; Maximum Quantity: 56; Number of Repeats: 2]*

insert:

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

[42] Schedule 1, Part 1, after entry for Escitalopram in the form Tablet 20 mg (as oxalate) *[Brand: Escitalopram Sandoz; Maximum Quantity: 56; Number of Repeats: 2]*

insert:

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

[43] Schedule 1, Part 1, entries for Fentanyl in the form Transdermal patch 2.1 mg

omit:

Fentanyl	Transdermal patch 2.1 mg	Transdermal	Durogesic 12	JC	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 2.1 mg	Transdermal	Durogesic 12	JC	MP NP	C11696	P11696	10	0	V11696	5

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[44] Schedule 1, Part 1, entries for Fentanyl in the form Transdermal patch 4.2 mg

omit:

Fentanyl	Transdermal patch 4.2 mg	Transdermal	Durogesic 25	JC	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 4.2 mg	Transdermal	Durogesic 25	JC	MP NP	C11696	P11696	10	0	V11696	5

[45] Schedule 1, Part 1, entries for Fentanyl in the form Transdermal patch 8.4 mg

omit:

Fentanyl	Transdermal patch 8.4 mg	Transdermal	Durogesic 50	JC	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 8.4 mg	Transdermal	Durogesic 50	JC	MP NP	C11696	P11696	10	0	V11696	5

[46] Schedule 1, Part 1, entries for Fentanyl in the form Transdermal patch 12.6 mg

omit:

Fentanyl	Transdermal patch 12.6 mg	Transdermal	Durogesic 75	JC	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 12.6 mg	Transdermal	Durogesic 75	JC	MP NP	C11696	P11696	10	0	V11696	5

[47] Schedule 1, Part 1, entries for Fentanyl in the form Transdermal patch 16.8 mg

omit:

Fentanyl	Transdermal patch 16.8 mg	Transdermal	Durogesic 100	JC	MP NP	C15994 C15996 C16000	P15994 P15996 P16000	5	0	V15994 V15996 V16000	5
Fentanyl	Transdermal patch 16.8 mg	Transdermal	Durogesic 100	JC	MP NP	C11696	P11696	10	0	V11696	5

[48] Schedule 1, Part 1, entries for Fluorouracil

substitute:

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Fluorouracil	Injection 500 mg in 10 mL	Injection	Fluorouracil Accord	OC	MP	C6266 C6297		See Note 3	See Note 3	1	D(100)	
Fluorouracil	Injection 1000 mg in 20 mL	Injection	Fluorouracil Accord	OC	MP	C6266 C6297		See Note 3	See Note 3	1	D(100)	
Fluorouracil	Injection 2500 mg in 50 mL	Injection	Fluorouracil Accord	OC	MP	C6266 C6297		See Note 3	See Note 3	1	D(100)	
Fluorouracil	Injection 5000 mg in 100 mL	Injection	Fluorouracil Accord	OC	MP	C6266 C6297		See Note 3	See Note 3	1	D(100)	

[49] Schedule 1, Part 1, after entry for Fosinopril in the form Tablet containing fosinopril sodium 20 mg *[Brand: Monace 20]*

insert:

Foslevodopa with foscarbidopa	Solution for subcutaneous infusion containing foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL	Injection	Vyalev	VE	MP NP	C16882	P16882	28	5	7		
Foslevodopa with foscarbidopa	Solution for subcutaneous infusion containing foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL	Injection	Vyalev	VE	MP	C16812	P16812	28	5	7		
Foslevodopa with foscarbidopa	Solution for subcutaneous infusion containing foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL	Injection	Vyalev	VE	MP	C16812 C16883	P16812 P16883	28	5	7	C(100)	
Foslevodopa with foscarbidopa	Solution for subcutaneous infusion containing foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL	Injection	Vyalev	VE	MP NP	C16951	P16951	56	5	7		
Foslevodopa with foscarbidopa	Solution for subcutaneous infusion containing foslevodopa 2400 mg with foscarbidopa 120 mg in	Injection	Vyalev	VE	MP	C16853	P16853	56	5	7		

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	10 mL											
Foslevodopa with foscarbidopa	Solution for subcutaneous infusion containing foslevodopa 2400 mg with foscarbidopa 120 mg in 10 mL	Injection	Vyalev	VE	MP	C16853 C16972	P16853 P16972	56	5		7	C(100)

[50] Schedule 1, Part 1, entries for Granisetron in the form Concentrated injection 3 mg (as hydrochloride) in 3 mL

omit:

Granisetron	Concentrated injection 3 mg (as hydrochloride) in 3 mL	Injection	Granisetron-AFT	AE	MP NP	C4077 C4092		1	0	V4077	1	
Granisetron	Concentrated injection 3 mg (as hydrochloride) in 3 mL	Injection	Granisetron-AFT	AE	MP	C4139		1	0	V4139	1	C(100)

[51] Schedule 1, Part 1, entries for Hydromorphone in the form Oral solution containing hydromorphone hydrochloride 1mg per mL, 1mL (S19A)

omit from the column headed "Form" (all instances): Oral solution containing hydromorphone hydrochloride 1mg per mL, 1mL (S19A)

substitute (all instances): Oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL (S19A)

[52] Schedule 1, Part 1, entries for Insect allergen extract-yellow jacket venom

omit:

Insect allergen extract-yellow jacket venom	Injection set containing 550 micrograms with diluent	Injection	Hymenoptera Yellow Jacket Venom	DE	MP		1	0		1	

[53] Schedule 1, Part 1, entries for Ipilimumab

substitute:

Ipilimumab	Injection concentrate for I.V. infusion 50 mg in 10 mL	Injection	Yervoy	BQ	MP	C6562 C6585 C8555 C11391 C11478 C11930 C16936	See Note 3	See Note 3		1	D(100)
Ipilimumab	Injection concentrate for I.V. infusion 200 mg in 40 mL	Injection	Yervoy	BQ	MP	C6562 C6585 C16936	See Note 3	See Note 3		1	D(100)

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[54] Schedule 1, Part 1, after entry for Isotretinoin in the form Capsule 20 mg *[Brand: Dermatane]*

insert:

Isotretinoin	Capsule 20 mg	Oral	Isotretinoin Dr.Reddy's	RZ	MP	C5224	60	3	30
Isotretinoin	Capsule 20 mg	Oral	Isotretinoin Dr.Reddy's	RZ	MP	C5224	60	3	60

[55] Schedule 1, Part 1, entry for Migalastat

omit from the column headed "Number of Repeats": 5 *substitute:* 6

[56] Schedule 1, Part 1, entries for Montelukast in the form Tablet, chewable, 4 mg (as sodium)

omit:

Montelukast	Tablet, chewable, 4 mg (as sodium)	Oral	Montelukast Mylan	AF	MP NP	C6666	P6666	28	5	28
Montelukast	Tablet, chewable, 4 mg (as sodium)	Oral	Montelukast Mylan	AF	MP NP	C15642	P15642	56	5	28

[57] Schedule 1, Part 1, entries for Morphine

omit:

Morphine	Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (RA-Morph)(S19A)	Oral	RA-Morph (NZ)	WZ	MP NP	C10764 C10770 C10777	P10764 P10770 P10777	200	0	V10764 V10770 V10777	200
Morphine	Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (RA-Morph)(S19A)	Oral	RA-Morph (NZ)	WZ	PDP	C10859		200	0		200
Morphine	Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (RA-Morph)(S19A)	Oral	RA-Morph (NZ)	WZ	MP NP	C11697	P11697	400	1	V11697	200

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

(a) omit from the column headed "Circumstances": C10119 C10120

(b) omit from the column headed "Circumstances": C14816

(c) insert in numerical order in the column headed "Circumstances": C16935 C16961 C16962

[59] Schedule 1, Part 1, entry for Nivolumab with relatlimab

(a) omit from the column headed "Circumstances": C16188

(b) insert in numerical order in the column headed "Circumstances": C16881

[60] Schedule 1, Part 1, entries for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg

omit:

Olmesartan with amlodipine and hydrochlorothiazide	Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg	Oral	Olmekar HCT 20/5/12.5	RF	MP NP	C4311	P4311	30	5	30
Olmesartan with amlodipine and hydrochlorothiazide	Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg	Oral	Olmekar HCT 20/5/12.5	RF	MP NP	C14272	P14272	60	5	30

[61] Schedule 1, Part 1, entries for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 12.5 mg

omit:

Olmesartan with amlodipine and hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 12.5 mg	Oral	Olmekar HCT 40/10/12.5	RF	MP NP	C4311	P4311	30	5	30
Olmesartan with amlodipine and	Tablet containing olmesartan medoxomil	Oral	Olmekar HCT 40/10/12.5	RF	MP NP	C14272	P14272	60	5	30

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hydrochlorothiazide	40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 12.5 mg									

[62] Schedule 1, Part 1, entries for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 25 mg

omit:

Olmesartan with amlodipine and hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 25 mg	Oral	Olmekar HCT 40/10/25	RF	MP NP	C4311	P4311	30	5	30
Olmesartan with amlodipine and hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 25 mg	Oral	Olmekar HCT 40/10/25	RF	MP NP	C14837	P14837	60	5	30

[63] Schedule 1, Part 1, entries for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg

omit:

Olmesartan with amlodipine and hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg	Oral	Olmekar HCT 40/5/12.5	RF	MP NP	C4311	P4311	30	5	30
Olmesartan with amlodipine and hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg	Oral	Olmekar HCT 40/5/12.5	RF	MP NP	C14272	P14272	60	5	30

[64] Schedule 1, Part 1, entries for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 25 mg

omit:

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Olmesartan with amlodipine and hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 25 mg	Oral	Olmekar HCT 40/5/25	RF	MP NP	C4311	P4311	30	5	30
Olmesartan with amlodipine and hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 25 mg	Oral	Olmekar HCT 40/5/25	RF	MP NP	C14272	P14272	60	5	30

[65] Schedule 1, Part 1, entries for Omalizumab

substitute:

Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled pen	Injection	Xolair	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection	Omlyclo	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection	Xolair	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Omalizumab	Injection 150 mg in 1 mL single dose pre-filled pen	Injection	Xolair	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Omalizumab	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection	Omlyclo	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
Omalizumab	Injection 300 mg in 2 mL single dose pre-filled pen	Injection	Xolair	NV	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[66] Schedule 1, Part 1, entries for Paroxetine

omit:

Paroxetine	Tablet 20 mg (as hydrochloride)	Oral	Noumed Paroxetine	VO	MP NP	C4755 C6277 C6636	P4755 P6277 P6636	30	5	30
Paroxetine	Tablet 20 mg (as hydrochloride)	Oral	Noumed Paroxetine	VO	MP NP	C15582 C15666 C15722	P15582 P15666 P15722	60	2	30

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

(a) omit from the column headed "Circumstances": C14817 C14818

(b) insert in numerical order in the column headed "Circumstances": C16933 C16950

[68] Schedule 1, Part 1, omit entries for Quinapril with hydrochlorothiazide

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

insert:

Rivaroxaban	Tablet 15 mg	Oral	Relaban	NB	MP NP	C4269	P4269	28	5	28
Rivaroxaban	Tablet 15 mg	Oral	Relaban	NB	MP NP	C14301	P14301	56	5	28

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

insert:

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

[71] Schedule 1, Part 1, after entry for Rizatriptan in the form Tablet (orally disintegrating) 10 mg (as benzoate) *[Brand: RIXALT]*

insert:

Rizatriptan	Tablet (orally disintegrating) 10 mg (as benzoate)	Oral	Rizatriptan-Au	DZ	MP NP	C5141		4	5	2

[72] Schedule 1, Part 1, omit entry for Tenecteplase

[73] Schedule 1, Part 1, entries for Tenofovir in the form Tablet containing tenofovir disoproxil fumarate 300 mg

omit:

Tenofovir	Tablet containing tenofovir disoproxil fumarate 300 mg	Oral	Tenofovir APOTEX	TX	MP NP	C10362	P10362	60	2	30	D(100)
Tenofovir	Tablet containing tenofovir	Oral	Tenofovir	TX	MP	C6980 C6982	P6980 P6982	60	5	30	D(100)

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	disoproxil fumarate 300 mg		APOTEX		NP	C6983 C6984 C6992 C6998	P6983 P6984 P6992 P6998				

[74] Schedule 1, Part 1, entries for Tenofovir with emtricitabine

omit:

Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A)	Oral	Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA)	KQ	MP NP	C11143	30	2	30	
Tenofovir with emtricitabine	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A)	Oral	Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA)	KQ	MP NP	C6985 C6986	60	5	30	C(100)

[75] Schedule 1, Part 1, entries for Ustekinumab

substitute:

Ustekinumab	Injection 45 mg in 0.5 mL	Injection	Stelara	JC	MP	C16818	P16818	1	0	1	
Ustekinumab	Injection 45 mg in 0.5 mL	Injection	Stelara	JC	MP	C12156 C16836 C16856 C16862 C16887 C16896 C16924 C16925 C16927 C16968 C16969 C16976	P12156 P16836 P16856 P16862 P16887 P16896 P16924 P16925 P16927 P16968 P16969 P16976	1	1	1	
Ustekinumab	Injection 45 mg in 0.5 mL	Injection	Stelara	JC	MP	C11120 C12334 C16819 C16832 C16838 C16857 C16868 C16885 C16894 C16899 C16900 C16901 C16910 C16920 C16922 C16937	P11120 P12334 P16819 P16832 P16838 P16857 P16868 P16885 P16894 P16899 P16900 P16901 P16910 P16920 P16922 P16937	1	2	1	

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						C16938	P16938			
Ustekinumab	Injection 45 mg in 0.5 mL	Injection	Stelara	JC	MP	C16821 C16824 C16863 C16889 C16890 C16946	P16821 P16824 P16863 P16889 P16890 P16946	2	0	1
Ustekinumab	Injection 45 mg in 0.5 mL single use pre-filled syringe	Injection	Steqeyma	EW	MP	C16818	P16818	1	0	1
Ustekinumab	Injection 45 mg in 0.5 mL single use pre-filled syringe	Injection	Steqeyma	EW	MP	C12156 C16835 C16854 C16856 C16862 C16886 C16887 C16896 C16911 C16925 C16927 C16967	P12156 P16835 P16854 P16856 P16862 P16886 P16887 P16896 P16911 P16925 P16927 P16967	1	1	1
Ustekinumab	Injection 45 mg in 0.5 mL single use pre-filled syringe	Injection	Steqeyma	EW	MP	C11120 C12334 C16819 C16832 C16838 C16857 C16868 C16885 C16894 C16899 C16900 C16901 C16910 C16920 C16922 C16937 C16938	P11120 P12334 P16819 P16832 P16838 P16857 P16868 P16885 P16894 P16899 P16900 P16901 P16910 P16920 P16922 P16937 P16938	1	2	1
Ustekinumab	Injection 45 mg in 0.5 mL single use pre-filled syringe	Injection	Steqeyma	EW	MP	C16821 C16824 C16863 C16889 C16890	P16821 P16824 P16863 P16889 P16890	2	0	1
Ustekinumab	Injection 45 mg in 0.5 mL single use pre-filled syringe	Injection	Steqeyma	EW	MP	C16913	P16913	2	2	1
Ustekinumab	Injection 90 mg in 1 mL single use pre-filled syringe	Injection	Stelara	JC	MP	C14801 C16828 C16829 C16917 C16918 C16944	P14801 P16828 P16829 P16917 P16918 P16944	1	0	1
Ustekinumab	Injection 90 mg in 1 mL single use pre-filled syringe	Injection	Stelara	JC	MP	C16915 C16916 C16919 C16943 C16973	P16915 P16916 P16919 P16943 P16973	1	1	1
Ustekinumab	Injection 90 mg in 1 mL single use pre-filled syringe	Injection	Steqeyma	EW	MP	C14801 C16821 C16824 C16828 C16829 C16863 C16889 C16890	P14801 P16821 P16824 P16828 P16829 P16863 P16889 P16890	1	0	1

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						C16917 C16918 C16944	P16917 P16918 P16944				
Ustekinumab	Injection 90 mg in 1 mL single use pre-filled syringe	Injection	Steqeyma	EW	MP	C12156 C16835 C16862 C16886 C16887 C16896 C16909 C16911 C16915 C16916 C16919 C16927 C16943 C16945 C16967 C16973	P12156 P16835 P16862 P16886 P16887 P16896 P16909 P16911 P16915 P16916 P16919 P16927 P16943 P16945 P16967 P16973	1	1	1	
Ustekinumab	Injection 90 mg in 1 mL single use pre-filled syringe	Injection	Steqeyma	EW	MP	C11120 C12334 C16819 C16832 C16838 C16857 C16868 C16894 C16900 C16901 C16913 C16920 C16922 C16938	P11120 P12334 P16819 P16832 P16838 P16857 P16868 P16894 P16900 P16901 P16913 P16920 P16922 P16938	1	2	1	
Ustekinumab	Solution for I.V. infusion 130 mg in 26 mL	Injection	Stelara	JC	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)
Ustekinumab	Solution for I.V. infusion 130 mg in 26 mL	Injection	Steqeyma	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	PB(100)

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

insert:

Varenicline	Box containing 11 tablets 0.5 mg and 42 tablets 1 mg	Oral	Varenicline Lupin	GQ	MP NP	C6871	1	0	1

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

insert:

Varenicline	Tablet 1 mg	Oral	Varenicline Lupin	GQ	MP NP	C6885	P6885	56	2	56
Varenicline	Tablet 1 mg	Oral	Varenicline Lupin	GQ	MP NP	C7483	P7483	112	0	56

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[78] Schedule 1, Part 2, after entry for Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides

insert:

Amino acid formula with vitamins and minerals without lysine and low in tryptophan	Sachets containing oral powder 24 g, 30 (GA gel)	Oral	GA gel	VF	1
Betaxolol	Eye drops, solution, 5 mg (as hydrochloride) per mL, 5 mL	Application to the eye	Betoptic	NV	1

[79] Schedule 1, Part 2, omit entry for Glycomacropeptide and essential amino acids with vitamins and minerals

[80] Schedule 1, Part 2, omit entry for Protein hydrolysate formula with medium chain triglycerides

[81] Schedule 1, Part 2, after entry for Semaglutide

insert:

Tenecteplase	Powder for injection 50 mg with solvent	Injection	Metalyse	BY	1

[82] Schedule 4, Part 1, entry for Circumstances Code "C4389"

omit from the column headed "Listed Drug": Quinapril with hydrochlorothiazide

[83] Schedule 4, Part 1, omit entry for Circumstances Code "C5783"

[84] Schedule 4, Part 1, entry for Circumstances Code "C6696"

omit from the column headed "Listed Drug": Ustekinumab

[85] Schedule 4, Part 1, omit entry for Circumstances Code "C8891"

[86] Schedule 4, Part 1, omit entry for Circumstances Code "C8987"

[87] Schedule 4, Part 1, entry for Circumstances Code "C9063"

omit from the column headed "Listed Drug": Ustekinumab

[88] Schedule 4, Part 1, omit entry for Circumstances Code "C9116"

[89] Schedule 4, Part 1, omit entry for Circumstances Code "C9122"

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[90] **Schedule 4, Part 1, omit entry for Circumstances Code "C9160"**

[91] **Schedule 4, Part 1, omit entry for Circumstances Code "C9175"**

[92] **Schedule 4, Part 1, omit entry for Circumstances Code "C9176"**

[93] **Schedule 4, Part 1, omit entry for Circumstances Code "C9655"**

[94] **Schedule 4, Part 1, omit entry for Circumstances Code "C9656"**

[95] **Schedule 4, Part 1, omit entry for Circumstances Code "C9657"**

[96] **Schedule 4, Part 1, omit entry for Circumstances Code "C9710"**

[97] **Schedule 4, Part 1, omit entry for Circumstances Code "C9711"**

[98] **Schedule 4, Part 1, omit entry for Circumstances Code "C10119"**

[99] **Schedule 4, Part 1, omit entry for Circumstances Code "C10120"**

[100] **Schedule 4, Part 1, omit entry for Circumstances Code "C11119"**

[101] **Schedule 4, Part 1, omit entry for Circumstances Code "C11145"**

[102] **Schedule 4, Part 1, omit entry for Circumstances Code "C11153"**

[103] **Schedule 4, Part 1, omit entry for Circumstances Code "C11161"**

[104] **Schedule 4, Part 1, entry for Circumstances Code "C12156"**

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

[105] **Schedule 4, Part 1, omit entry for Circumstances Code "C12285"**

[106] **Schedule 4, Part 1, omit entry for Circumstances Code "C13927"**

[107] **Schedule 4, Part 1, omit entry for Circumstances Code "C13952"**

[108] **Schedule 4, Part 1, omit entry for Circumstances Code "C13955"**

[109] **Schedule 4, Part 1, omit entry for Circumstances Code "C13988"**

[110] **Schedule 4, Part 1, omit entry for Circumstances Code "C14018"**

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[111] Schedule 4, Part 1, entry for Circumstances Code "C14238"

omit from the column headed "Listed Drug": Betaxolol

[112] Schedule 4, Part 1, omit entry for Circumstances Code "C14415"

[113] Schedule 4, Part 1, omit entry for Circumstances Code "C14442"

[114] Schedule 4, Part 1, omit entry for Circumstances Code "C14543"

[115] Schedule 4, Part 1, omit entry for Circumstances Code "C14558"

[116] Schedule 4, Part 1, omit entry for Circumstances Code "C14572"

[117] Schedule 4, Part 1, omit entry for Circumstances Code "C14573"

[118] Schedule 4, Part 1, omit entry for Circumstances Code "C14628"

[119] Schedule 4, Part 1, omit entry for Circumstances Code "C14636"

[120] Schedule 4, Part 1, omit entry for Circumstances Code "C14643"

[121] Schedule 4, Part 1, omit entry for Circumstances Code "C14758"

[122] Schedule 4, Part 1, omit entry for Circumstances Code "C14787"

[123] Schedule 4, Part 1, omit entry for Circumstances Code "C14806"

[124] Schedule 4, Part 1, omit entry for Circumstances Code "C14808"

[125] Schedule 4, Part 1, omit entry for Circumstances Code "C14816"

[126] Schedule 4, Part 1, omit entry for Circumstances Code "C14817"

[127] Schedule 4, Part 1, omit entry for Circumstances Code "C14818"

[128] Schedule 4, Part 1, omit entry for Circumstances Code "C15450"

[129] Schedule 4, Part 1, omit entry for Circumstances Code "C15518"

[130] Schedule 4, Part 1, omit entry for Circumstances Code "C16188"

[131] Schedule 4, Part 1, omit entry for Circumstances Code "C16771"

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[132] Schedule 4, Part 1, after entry for Circumstances Code "C16809"

insert:

C16812	P16812	CN16812	Foslevodopa with foscarbidopa	Advanced Parkinson disease Must be treated by a specialist physician; or Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease. Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 16812
C16814	P16814	CN16814	Durvalumab	Advanced, metastatic or recurrent endometrial carcinoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition. Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime. Retain all pathology imaging and investigative test results in the patient's medical records. Patients with a body weight of 30 kg or less during continuing treatment must receive weight-based dosing, equivalent to durvalumab 20 mg/kg, until weight is greater than 30 kg.	Compliance with Authority Required procedures - Streamlined Authority Code 16814
C16818	P16818	CN16818	Ustekinumab	Severe chronic plaque psoriasis First continuing, Subsequent continuing treatment - balance of supply (Whole body, or, face/hand/foot) Must be treated by a dermatologist; AND Patient must be undergoing current PBS-subsidised treatment with this biological medicine, but the full number of repeats available under the continuing treatment phase was not prescribed.	Compliance with Authority Required procedures
C16819	P16819	CN16819	Ustekinumab	Severe chronic plaque psoriasis Initial 1 treatment (Whole body) - biological medicine-naive patient Must be treated by a dermatologist. Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND	Compliance with Written Authority Required procedures

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	The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have lesions present for at least 6 months from the time of initial diagnosis; AND Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be under 18 years of age. Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application. Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy: (a) A Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of the last pre-requisite therapy. A PASI assessment must have been completed for each pre-requisite treatment trialled, preferably when the patient was on treatment, but no longer than 4 weeks following cessation of that pre-requisite treatment. Provide in this authority application, and document in the patient's medical records, each of: (i) the name of each prior therapy trialled that meets the above requirements - state at least 2; (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies); (iii) the PASI score that followed each prior therapy trialled;

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				(iv) the date the PASI scores were determined. Provide a baseline PASI score to be referenced in any future authority applications that continue treatment. This PASI score may be any of: (i) a current PASI score, (ii) a PASI score present prior to, or, after a pre-requisite non-biological medicine.	
C16821	P16821	CN16821	Ustekinumab	Severe Crohn disease Balance of supply Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment. or The treatment must provide no more than the balance of up to 24 weeks therapy available under first continuing treatment or subsequent continuing treatment.	Compliance with Authority Required procedures
C16824	P16824	CN16824	Ustekinumab	Severe Crohn disease Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently	Compliance with Written Authority Required procedures

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	approved PBS-subsidised biological medicine for this condition; AND Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; or Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; or Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application; AND Patient must have evidence of intestinal inflammation; or Patient must be assessed clinically as being in a high faecal output state; or Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction. Patient must be at least 18 years of age. Applications for authorisation must be made in writing and must include: (a) details of the two proposed prescriptions; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iii) the date of the most recent clinical assessment. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the

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				mesentery. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for a total dose of 90 mg and no repeats. A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. 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.	
C16828	P16828	CN16828	Ustekinumab	Moderate to severe ulcerative colitis Initial treatment - initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a gastroenterologist (code 87); or	Compliance with Written Authority Required procedures

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	Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have a Mayo clinic score greater than or equal to 6; or Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND The treatment must not exceed a single dose to be administered at week 8 under this restriction. Patient must be at least 18 years of age. 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), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. 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.

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				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 maximum of 16 weeks of treatment with this drug will be approved under this criterion. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats. Details of the accepted toxicities including severity can be found on the Services Australia website.	
C16829	P16829	CN16829	Ustekinumab	Complex refractory Fistulising Crohn disease Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have an externally draining enterocutaneous or rectovaginal fistula. Must be treated by a gastroenterologist (code 87). or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Applications for authorisation must be made in writing and must include: (1) details of the two proposed prescriptions; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.	Compliance with Written Authority Required procedures

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				An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.	
C16832	P16832	CN16832	Ustekinumab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by	Compliance with Written Authority Required procedures

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				evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16835	P16835	CN16835	Ustekinumab	Severe chronic plaque psoriasis Subsequent continuing treatment, Whole body Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16835

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				Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16836	P16836	CN16836	Ustekinumab	Severe chronic plaque psoriasis Subsequent continuing treatment, Whole body Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a	Compliance with Written Authority Required procedures

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				single injection. Up to a maximum of 1 repeat will be authorised. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16838	P16838	CN16838	Ustekinumab	Severe chronic plaque psoriasis Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years Must be treated by a dermatologist. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition for at least 5 years, if they have previously received PBS-subsidised treatment with a biological medicine for this condition and wish to commence a new treatment cycle; AND The condition must be affecting the whole body - all subsequent authority applications to this application will be made under treatment phases that feature the words 'whole body'; or	Compliance with Written Authority Required procedures

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				The condition must be limited to the face/hand/foot - all subsequent authority applications to this application will be made under treatment phases that feature the words 'face, hand, foot'; AND Patient must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; or The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be under 18 years of age. The most recent PASI assessment must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records. 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).	
C16853	P16853	CN16853	Foslevodopa with foscarbidopa	Advanced Parkinson disease Must be treated by a specialist physician; or Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease. Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND Patient must require continuous administration of foslevodopa without an overnight break. or Patient must require a total daily dose of more than 2,400 mg of foslevodopa.	Compliance with Authority Required procedures - Streamlined Authority Code 16853
C16854	P16854	CN16854	Ustekinumab	Severe psoriatic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with this drug for this	Compliance with Authority Required procedures - Streamlined Authority Code 16854

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				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 under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16856	P16856	CN16856	Ustekinumab	Severe psoriatic arthritis First continuing, Subsequent continuing treatment - balance of supply Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment	Compliance with Authority Required procedures

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				available under the above restriction.	
C16857	P16857	CN16857	Ustekinumab	Severe chronic plaque psoriasis Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient Must be treated by a dermatologist. Patient must be undergoing treatment for the first time with PBS-subsidised biological medicine for this PBS indication; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have the plaque or plaques of the face, or palm of hand or sole of foot present for at least 6 months from the time of initial diagnosis; AND Patient must have failed to achieve an adequate response to at least 2 of the following 3 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg or 10 mg per square metre weekly (whichever is lowest) for at least 6 weeks; (iii) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be under 18 years of age. Where treatment with any of the above-mentioned drugs was contraindicated according to the relevant TGA-approved Product Information, or where phototherapy was contraindicated, details must be provided at the time of application. Where intolerance to phototherapy, methotrexate and/or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following indicates failure to achieve an adequate response to prior phototherapy/methotrexate/acitretin therapy: (a) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling being rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy; or (b) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot,	Compliance with Written Authority Required procedures

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				as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the last pre-requisite therapy Provide in this authority application, and document in the patient's medical records, each of: (i) the name of each prior therapy trialled that meets the above requirements - state at least 2; (ii) the date of commencement and cessation of each prior therapy trialled, as well as the dosage (for drug therapies); (iii) whether failure type (a) or (b) as described above occurred for each prior therapy trialled; (iv) the dates that response assessments were determined. Provide in this authority application at least one of the following to act as a baseline measurement and be referenced in any future authority applications that continue treatment: (v) for each of erythema, thickness and scaling, which of these are rated as severe or very severe (at least 2 must be rated as severe/very severe); (vi) the percentage area of skin (combined area of face, hands and feet) affected by this condition (must be at least 30%) prior to treatment with biological medicine.	
C16862	P16862	CN16862	Ustekinumab	Severe chronic plaque psoriasis First continuing treatment (Whole body) - treatment covering week 28 and onwards Must be treated by a dermatologist. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND Patient must have demonstrated an adequate response to treatment; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more,	Compliance with Written Authority Required procedures

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				or is sustained at this level, when compared with the baseline value for this treatment cycle. The assessment of response to treatment must be provided in this application and documented in the patient's medical records. The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.	
C16863	P16863	CN16863	Ustekinumab	Severe Crohn disease Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician; AND Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; AND Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; or Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; or Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction; AND Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; or Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; or Patient must have extensive intestinal inflammation affecting more than 50 cm of the	Compliance with Written Authority Required procedures

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	small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below. Patient must be at least 18 years of age. Applications for authorisation must be made in writing and must include: (a) details of the two proposed prescriptions; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and (iv) the date of the most recent clinical assessment. Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following: (a) patient must have evidence of intestinal inflammation; (b) patient must be assessed clinically as being in a high faecal output state; (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient. Evidence of intestinal inflammation includes: (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or (ii) faeces: higher than normal lactoferrin or calprotectin level; or (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for a total dose of 90 mg and no repeats. A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised Where fewer than 6 vials in total are requested at the time of the application, authority

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				approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. Details of the accepted toxicities including severity can be found on the Services Australia website. Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.	
C16868	P16868	CN16868	Ustekinumab	Severe chronic plaque psoriasis Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently	Compliance with Written Authority Required procedures

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				approved PBS-subsidised biological medicine for this condition; AND The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C16881	P16881	CN16881	Nivolumab with relatlimab	Unresectable Stage III or Stage IV malignant melanoma	Compliance with

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				Initial treatment Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; OR Patient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be uveal melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patient must weigh 40 kg or more; AND Patient must be at least 12 years of age. Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen. The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information. The prescription must include the amount of nivolumab with relatlimab (Opdualag) that is appropriate to be prescribed for the patient. For the purposes of PBS subsidy, the maximum amount requested is based on the nivolumab dose only. The prescribed amount of nivolumab must be expressed in milligrams.	Authority Required procedures - Streamlined Authority Code 16881
C16882	P16882	CN16882	Foslevodopa with foscarbidopa	Advanced Parkinson disease Maintenance therapy The treatment must have been commenced by a specialist physician; or The treatment must have been commenced by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease; AND Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy.	Compliance with Authority Required procedures - Streamlined Authority Code 16882
C16883	P16883	CN16883	Foslevodopa with foscarbidopa	Advanced Parkinson disease Must be treated by a specialist physician; or Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease. Patient must have severe disabling motor fluctuations not adequately controlled by	Compliance with Authority Required procedures - Streamlined Authority Code 16883

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				oral therapy.	
C16885	P16885	CN16885	Ustekinumab	Severe psoriatic arthritis Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or The condition must have a C-reactive protein (CRP) level greater than 15 mg per L; AND The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be at least 18 years of age. Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application. If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.	Compliance with Written Authority Required procedures

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				An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced 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.	
C16886	P16886	CN16886	Ustekinumab	Severe chronic plaque psoriasis Subsequent continuing treatment (Whole body) Must be treated by a dermatologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Whole body) - treatment covering week 28 and onwards restrictions; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The assessment of response to treatment must be provided in this application and	Compliance with Authority Required procedures - Streamlined Authority Code 16886

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				documented in the patient's medical records. The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.	
C16887	P16887	CN16887	Ustekinumab	Severe chronic plaque psoriasis First continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards Must be treated by a dermatologist. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must have been assessed for response to treatment after at least 12 weeks treatment with the preceding supply of this biological medicine; AND Patient must have demonstrated an adequate response to treatment; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The assessment of response to treatment must be provided in this application and documented in the patient's medical records.	Compliance with Written Authority Required procedures
C16889	P16889	CN16889	Ustekinumab	Severe Crohn disease First continuing treatment Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or	Compliance with Written Authority Required procedures

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	Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Applications for authorisation must be made in writing and must include: (a) details of the proposed prescription; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment. All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. An application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be conducted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Services Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

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				Where an assessment is not submitted within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. 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. 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; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks. Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested by telephone by contacting Services Australia and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend continuing treatment beyond 24 months.	
C16890	P16890	CN16890	Ustekinumab	Severe Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction. Patient must be at least 18 years of age. Applications for authorisation must be made in writing and must include:	Compliance with Written Authority Required procedures

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		(a) details of the two proposed prescriptions; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment; and (iv) the details of prior biological medicine treatment including the details of date and duration of treatment. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for a total dose of 90 mg and no repeats. A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period. To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to Services Australia no later than 4 weeks from the date of completion of treatment. 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

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				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.	
C16894	P16894	CN16894	Ustekinumab	Severe chronic plaque psoriasis Initial treatment - Initial 1, Whole body (new patient) Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application. Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met. The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application: (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as	Compliance with Written Authority Required procedures

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				assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment. (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment. (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]. At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C16896	P16896	CN16896	Ustekinumab	Severe chronic plaque psoriasis First continuing treatment, Whole body Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND	Compliance with Written Authority Required procedures

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				The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16899	P16899	CN16899	Ustekinumab	Severe psoriatic arthritis Initial treatment - Initial 1 (new patient) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of	Compliance with Written Authority Required procedures

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	psoriatic arthritis. Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months; AND Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; or Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be at least 18 years of age. Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application. Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application. The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application: an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and either (a) an active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active joints from the following list of major joints: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. 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.	

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				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.	
C16900	P16900	CN16900	Ustekinumab	Severe chronic plaque psoriasis Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the	Compliance with Written Authority Required procedures

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				patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include: (1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and (ii) details of prior biological treatment, including dosage, date and duration of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16901	P16901	CN16901	Ustekinumab	Severe chronic plaque psoriasis Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years Must be treated by a dermatologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be under 18 years of age. The authority application must be made in writing and must include: (1) details of the proposed prescription; and	Compliance with Written Authority Required procedures

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				(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). Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application. Response to preceding supply: An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. Change in therapy: If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because: (i) there is an absence of an adequate response to that treatment; or (ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above Recommencing therapy: If the patient is recommencing therapy, in relation to the last administered dose, state whether there was: (i) an absence of an adequate response; or (ii) an intolerance to that treatment; or (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above. The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.	
C16909	P16909	CN16909	Ustekinumab	Complex refractory Fistulising Crohn disease 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. Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].	Compliance with Authority Required procedures - Streamlined Authority Code 16909

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				An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.	
C16910	P16910	CN16910	Ustekinumab	Severe psoriatic arthritis Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 28 weeks treatment; or Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; or Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; AND The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restriction.	Compliance with Authority Required procedures
C16911	P16911	CN16911	Ustekinumab	Severe chronic plaque psoriasis Subsequent continuing treatment (Face, hand, foot) Must be treated by a dermatologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards restrictions; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy; OR The treatment must be in combination with methotrexate; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. An adequate response to treatment is defined as the plaque or plaques assessed prior	Compliance with Authority Required procedures - Streamlined Authority Code 16911

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				to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The assessment of response to treatment must be provided in this application and documented in the patient's medical records.	
C16913	P16913	CN16913	Ustekinumab	Severe Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 16913

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				Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested by telephone by contacting Services Australia and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend continuing treatment beyond 24 months.	
C16915	P16915	CN16915	Ustekinumab	Moderate to severe ulcerative colitis First continuing treatment Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. 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 or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. 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 sufficient quantity for up to 24 weeks of treatment under this restriction. 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	Compliance with Authority Required procedures

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				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.	
C16916	P16916	CN16916	Ustekinumab	Moderate to severe ulcerative colitis First continuing, Subsequent continuing treatment - balance of supply Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. 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 treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.	Compliance with Authority Required procedures
C16917	P16917	CN16917	Ustekinumab	Moderate to severe ulcerative colitis Initial treatment - Initial 1 (new patient) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; AND Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; or	Compliance with Written Authority Required procedures

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	Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent; AND Patient must have a Mayo clinic score greater than or equal to 6; or Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); AND The treatment must not exceed a single dose to be administered at week 8 under this restriction. Patient must be at least 18 years of age. 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), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) details of prior systemic drug therapy (dosage, date of commencement and duration of therapy). All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment. The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. 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. If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.	

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				If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.	
C16918	P16918	CN16918	Ustekinumab	Moderate to severe ulcerative colitis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND The treatment must not exceed a single dose to be administered at week 8 under this restriction. Patient must be at least 18 years of age. 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), which includes: (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and (ii) the details of prior biological medicine treatment including the details of date and duration of treatment. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent	Compliance with Written Authority Required procedures

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				course of PBS-subsidised biological medicine treatment, within the timeframes specified below. An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. A maximum of 16 weeks of treatment with this drug will be approved under this criterion. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats. Details of the accepted toxicities including severity can be found on the Services Australia website.	
C16919	P16919	CN16919	Ustekinumab	Complex refractory Fistulising Crohn disease Subsequent continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND 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. Must be treated by a gastroenterologist (code 87). or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or	Compliance with Written Authority Required procedures

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				Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. The most recent fistula assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.	
C16920	P16920	CN16920	Ustekinumab	Severe chronic plaque psoriasis Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. The most recent PASI assessment must be no more than 4 weeks old at the time of application. At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 2 repeats will be authorised. The authority application must be made in writing and must include:	Compliance with Written Authority Required procedures

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				(1) details of the proposed prescription(s); and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C16922	P16922	CN16922	Ustekinumab	Severe chronic plaque psoriasis Initial treatment - Initial 1, Face, hand, foot (new patient) Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin	Compliance with Written Authority Required procedures

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

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				To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.	
C16924	P16924	CN16924	Ustekinumab	Severe psoriatic arthritis Subsequent continuing treatment Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have previously received PBS-subsidised treatment with 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 under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of	Compliance with Written Authority Required procedures

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				passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion 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. 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.	
C16925	P16925	CN16925	Ustekinumab	Severe psoriatic arthritis First continuing treatment Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have 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;	Compliance with Written Authority Required procedures

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	AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced 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.

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				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.	
C16927	P16927	CN16927	Ustekinumab	Severe chronic plaque psoriasis First continuing treatment, Face, hand, foot Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same	Compliance with Written Authority Required procedures

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				affected area assessed at baseline. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. 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.	
C16932	P16932	CN16932	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 this drug; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be hormone receptor positive; AND The condition must be at high risk of recurrence at treatment initiation with this drug, with high risk being any of: (a) cancer cells in at least 4 positive axillary lymph nodes, (b) cancer cells in 1 to 3 positive axillary lymph nodes plus at least one of: (i) tumour size of at least 5 cm in size, (ii) grade 3 tumour histology (on the Nottingham grading system); AND The treatment must not be a PBS-subsidised benefit beyond whichever comes first: (i) a total of 2 years of active treatment (this includes any non-PBS-subsidised supply if applicable), (ii) disease recurrence/progression; AND The treatment must not be in combination with any of the following: (i) olaparib, (ii) pembrolizumab, (iii) ribociclib. Patient must be undergoing concurrent treatment with endocrine therapy where this drug is being prescribed as a PBS benefit. Retain all pathology imaging and investigative test results in the patient's medical records. PBS-subsidised treatment with CDK 4/6 inhibitors is restricted to one line of therapy at	Compliance with Authority Required procedures

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				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).	
C16933	P16933	CN16933	Pembrolizumab	Unresectable Stage III or Stage IV malignant melanoma Initial treatment - 6 weekly treatment regimen Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; OR Patient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a total of 3 doses under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 16933
C16935	P16935	CN16935	Nivolumab	Stage IIIB, IIIC, IIID or Stage IV malignant melanoma Initial treatment The treatment must be in addition to complete surgical resection; AND Patient must have a WHO performance status of 1 or less; AND Patient must not have received prior PBS-subsidised treatment for this condition; AND The treatment must commence within 12 weeks of complete resection; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. When nivolumab is initially prescribed as a 3-weekly dosing regimen, patients must only receive a maximum of 240 mg every 3 weeks for 2 cycles (i.e., 1 repeat). When prescribed as a weight based or flat dose adjuvant regimen, patients must only receive a maximum of 240 mg every 2 weeks or 480 mg every 4 weeks for a maximum of 12 months of adjuvant treatment.	Compliance with Authority Required procedures
C16936	P16936	CN16936	Ipilimumab	Stage III or Stage IV malignant melanoma Induction treatment Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16936

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				The condition must not be ocular or uveal melanoma; AND The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition. Prescribed amounts must be consistent with the treatment protocol used for an individual patient. Prescribers may apply through this restriction for patients initiated on 80 mg every 3 weeks for 2 cycles (i.e., 1 repeat). Prescribers may also apply through this restriction when the condition progresses to unresectable/metastatic melanoma at the recommended dosing regimen. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	
C16937	P16937	CN16937	Ustekinumab	Severe psoriatic arthritis Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Must be treated by a rheumatologist; or Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be at least 18 years of age. An adequate response to treatment is defined as: an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following major active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of	Compliance with Written Authority Required procedures

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				passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form. An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below. Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not provided, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16938	P16938	CN16938	Ustekinumab	Severe chronic plaque psoriasis Initial 2 treatment (Face, hand, foot) - Change or recommencement of treatment after a break in biological medicine of less than 5 years Must be treated by a dermatologist. Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND	Compliance with Written Authority Required procedures

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		Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment 3 times for this condition within this treatment cycle; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must not receive more than 28 weeks of treatment under this restriction. Patient must be under 18 years of age. 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). Where the patient is changing from treatment with etanercept a baseline PASI measurement must be provided with this authority application. Response to preceding supply: An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. Change in therapy: If the patient is changing therapy, in relation to the biological medicine that the patient is changing from, state whether the patient is changing therapy because: (i) there is an absence of an adequate response to that treatment; or (ii) there was an intolerance to that treatment; or (iii) there was an adequate response, but a change in treatment has been made for reasons other than the 2 mentioned above Recommencing therapy: If the patient is recommencing therapy, in relation to the last administered dose, state whether there was: (i) an absence of an adequate response; or (ii) an intolerance to that treatment; or (iii) an adequate response, but a break in therapy was necessary for reasons other than the 2 mentioned above. The assessment of response to treatment and the reason for changing therapy must be provided in this application and documented in the patient's medical records.

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C16943	P16943	CN16943	Ustekinumab	Complex refractory Fistulising Crohn disease First continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug. Must be treated by a gastroenterologist (code 87). or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response is defined as: (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient. The most recent fistula assessment must be no more than 1 month old at the time of application. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks.	Compliance with Written Authority Required procedures
C16944	P16944	CN16944	Ustekinumab	Complex refractory Fistulising Crohn disease Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle. Must be treated by a gastroenterologist (code 87). or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]. or Must be treated by a consultant physician [general medicine specialising in	Compliance with Written Authority Required procedures

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				gastroenterology (code 82)]. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted between 8 and 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Applications for authorisation must be made in writing and must include: (1) details of the two proposed prescriptions; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following: (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and (ii) details of prior biological medicine treatment including details of date and duration of treatment. Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats. The most recent fistula assessment must be no more than 4 weeks old at the time of application. A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.	
C16945	P16945	CN16945	Ustekinumab	Moderate to severe ulcerative colitis Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); OR	Compliance with Authority Required procedures - Streamlined

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				Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. 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 or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response. 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.	Authority Code 16945
C16946	P16946	CN16946	Ustekinumab	Severe Crohn disease Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND	Compliance with Written Authority Required procedures

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	Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Applications for authorisation must be made in writing and must include: (a) details of the proposed prescription; and (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following: (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and (iii) the date of clinical assessment. All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. An application for continuing treatment with this drug must include a measurement of response to the most recent course of PBS-subsidised therapy. This assessment must be conducted no later than 4 weeks from the cessation of that treatment course. If the application is the first application for continuing treatment with this drug, it must be accompanied by an assessment of response to a minimum of 12 weeks of treatment with the initial treatment course. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Services Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion. Where an assessment is not submitted within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be	

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				eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. 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; up to 1 repeat will be authorised for patients whose dosing frequency is every 12 weeks. Up to a maximum of 2 repeats will be authorised for patients whose dosing frequency is every 8 weeks. Where an inadequate number of repeats are requested at the time of the application to complete a course of 24 weeks treatment, authority approvals for sufficient repeats to complete 24 weeks of treatment may be requested by telephone by contacting Services Australia and applying through the Balance of Supply restriction. Under no circumstances will telephone approvals be granted for treatment that would otherwise extend continuing treatment beyond 24 months.	
C16950	P16950	CN16950	Pembrolizumab	Unresectable Stage III or Stage IV malignant melanoma Initial treatment - 3 weekly treatment regimen Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; OR Patient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a total of 6 doses under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 16950
C16951	P16951	CN16951	Foslevodopa with foscarbidopa	Advanced Parkinson disease Maintenance therapy The treatment must have been commenced by a specialist physician; or The treatment must have been commenced by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease; AND Patient must have severe disabling motor fluctuations not adequately controlled by	Compliance with Authority Required procedures - Streamlined Authority Code 16951

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				oral therapy; AND Patient must require continuous administration of foslevodopa without an overnight break. or Patient must require a total daily dose of more than 2,400 mg of foslevodopa.	
C16953	P16953	CN16953	Durvalumab	Advanced, metastatic or recurrent endometrial carcinoma Initial treatment covering the first 6 treatment cycles Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test; AND The condition must be unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy; AND The treatment must be initiated in combination with platinum-containing chemotherapy; AND The condition must be, at treatment initiation with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic therapy; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation. Retain all pathology imaging and investigative test results in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 16953
C16961	P16961	CN16961	Nivolumab	Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; OR Patient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 16961

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C16962	P16962	CN16962	Nivolumab	Stage IIIB, IIIC, IIID or Stage IV malignant melanoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have undergone surgical resection; AND Patient must not have experienced disease recurrence; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy. When prescribed as a weight based or flat dose adjuvant regimen, patients must receive a maximum of 240 mg every 2 weeks or 480 mg every 4 weeks for a maximum of 12 months of adjuvant treatment.	Compliance with Authority Required procedures
C16967	P16967	CN16967	Ustekinumab	Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction. Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The measurement of response to the prior course of therapy must be documented in the patient's medical notes. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in	Compliance with Authority Required procedures - Streamlined Authority Code 16967

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				this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.	
C16968	P16968	CN16968	Ustekinumab	Severe chronic plaque psoriasis Subsequent continuing treatment (Face, hand, foot) Must be treated by a dermatologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Face, hand, foot) - treatment covering week 28 and onwards restrictions; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. The assessment of response to treatment must be provided in this application and documented in the patient's medical records.	Compliance with Written Authority Required procedures
C16969	P16969	CN16969	Ustekinumab	Severe chronic plaque psoriasis Subsequent continuing treatment (Whole body) Must be treated by a dermatologist. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment (Whole body) - treatment covering week 28 and onwards restrictions; AND Patient must have demonstrated an adequate response to treatment with this drug; AND	Compliance with Written Authority Required procedures

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				The treatment must be as systemic monotherapy; or The treatment must be in combination with methotrexate; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An adequate response to treatment is defined as: A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle. The assessment of response to treatment must be provided in this application and documented in the patient's medical records. The same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of gaining approval for the remainder of 24 weeks treatment.	
C16972	P16972	CN16972	Foslevodopa with foscarbidopa	Advanced Parkinson disease Must be treated by a specialist physician; or Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease. Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy; AND Patient must require continuous administration of foslevodopa without an overnight break. or Patient must require a total daily dose of more than 2,400 mg of foslevodopa.	Compliance with Authority Required procedures - Streamlined Authority Code 16972
C16973	P16973	CN16973	Ustekinumab	Moderate to severe ulcerative colitis Subsequent continuing treatment Must be treated by a gastroenterologist (code 87); or Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; or Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]. Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND	Compliance with Authority Required procedures

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				Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; AND Patient must not receive more than 24 weeks of treatment under this restriction. Patient must be at least 18 years of age. Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug. 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 sufficient quantity for up to 24 weeks of treatment under this restriction. 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.	
C16976	P16976	CN16976	Ustekinumab	Severe chronic plaque psoriasis Subsequent continuing treatment, Face, hand, foot Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND Patient must have demonstrated an adequate response to treatment with this drug; AND The treatment must be as systemic monotherapy (other than methotrexate); AND Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.	Compliance with Written Authority Required procedures

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	Patient must be at least 18 years of age. Must be treated by a dermatologist. An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing: (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle. At the time of the authority application, medical practitioners should request the appropriate dosage, based on the weight of the patient, to provide sufficient for a single injection. Up to a maximum of 1 repeat will be authorised. The authority application must be made in writing and must include: (a) details of the proposed prescription(s); and (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition. The most recent PASI assessment must be no more than 4 weeks old at the time of application. Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug. The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline. It is recommended that an application for the continuing treatment is submitted to Services Australia no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

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[133] Schedule 5, entries for Abiraterone

insert in the column headed "Brand" after entry for the Brand "Abiraterone-Teva" (all instances): ZYRON

[134] Schedule 5, entries for Aciclovir

substitute:

Aciclovir	GRP-22959	Eye ointment 30 mg per g, 4.5 g	Application to the eye	ViruPOS XOROX
Aciclovir	GRP-15446	Tablet 200 mg	Oral	Aciclovir APOTEX Aciclovir GH Aciclovir Sandoz ACICLOVIR-WGR APO-Aciclovir ARX-ACICLOVIR
Aciclovir	GRP-19838	Tablet 800 mg	Oral	Aciclovir Sandoz ACICLOVIR-WGR APO-Aciclovir ARX-ACICLOVIR

[135] Schedule 5, entries for Dabigatran etexilate in each of the forms: Capsule 110 mg (as mesilate); and Capsule 150 mg (as mesilate)

insert in the column headed "Brand" after entry for the Brand "Dabigatran Sandoz": Dabigatran Viatris

[136] Schedule 5, entry for Dabigatran etexilate in the form Capsule 75 mg (as mesilate)

insert in the column headed "Brand" after entry for the Brand "ARX-Dabigatran": Dabigatran Viatris

[137] Schedule 5, after entry for Deferasirox *[GRP-28210]*

insert:

Denosumab	GRP-29945	Injection 120 mg in 1.7 mL	Injection	Wyost Xgeva
Denosumab	GRP-29965	Injection 60 mg in 1 mL pre-filled syringe	Injection	Jubbonti Prolia

[138] Schedule 5, after entry for Doxycycline in the form Tablet 50 mg (as monohydrate)

insert:

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Drospirenone with ethinylestradiol	GRP-29943	Pack containing 21 tablets 3 mg drospirenone with 30 micrograms ethinylestradiol and 7 inert tablets	Oral	Isabelle Rosalee Yasmin Yelena
Drospirenone with ethinylestradiol	GRP-29944	Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol and 4 inert tablets	Oral	Bella Rosie YANA
Drospirenone with ethinylestradiol	GRP-29944	Pack containing 24 tablets 3 mg drospirenone with 20 micrograms ethinylestradiol (as betadex clathrate) and 4 inert tablets	Oral	Yaz

[139] Schedule 5, entries for Escitalopram

insert in the column headed "Brand" after entry for the Brand "Escitalopram Sandoz" (all instances): ESCITALOPRAM-WGR

[140] Schedule 5, entry for Fentanyl in the form Transdermal patch 12.6 mg

omit from the column headed "Brand": Durogesic 75

[141] Schedule 5, entry for Fentanyl in the form Transdermal patch 4.2 mg

omit from the column headed "Brand": Durogesic 25

[142] Schedule 5, entry for Fentanyl in the form Transdermal patch 8.4 mg

omit from the column headed "Brand": Durogesic 50

[143] Schedule 5, entry for Fentanyl in the form Transdermal patch 16.8 mg

omit from the column headed "Brand": Durogesic 100

[144] Schedule 5, entry for Fentanyl in the form Transdermal patch 2.1 mg

omit from the column headed "Brand": Durogesic 12

[145] Schedule 5, omit entry for Granisetron

[146] Schedule 5, entry for Hydromorphone in the form Oral solution containing hydromorphone hydrochloride 1mg per mL, 1mL (S19A)

omit from the column headed "Form": Oral solution containing hydromorphone hydrochloride 1mg per mL, 1mL (S19A)
substitute: Oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL (S19A)

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[147] Schedule 5, entries for Isotretinoin in each of the forms: Capsule 10 mg; and Capsule 20 mg

substitute:

Isotretinoin	GRP-19867	Capsule 10 mg	Oral	APO-Isotretinoin Dermatane Isotretinoin GX Isotretinoin Lupin ISOTRETINOIN-WGR Oratane
Isotretinoin	GRP-22820	Capsule 20 mg	Oral	APO-Isotretinoin Dermatane Isotretinoin Dr.Reddy's Isotretinoin GX Isotretinoin Lupin ISOTRETINOIN-WGR Oratane Pharmacor Isotretinoin Roaccutane

[148] Schedule 5, entry for Montelukast *[GRP-19556]*

omit from the column headed "Brand": Montelukast Mylan

[149] Schedule 5, entries for Morphine

omit:

Morphine	GRP-28497	Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (RA-Morph)(S19A)	Oral	RA-Morph (NZ)

[150] Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide *[GRP-23699]*

omit from the column headed "Brand": Olmekar HCT 40/5/25

[151] Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide *[GRP-23700]*

omit from the column headed "Brand": Olmekar HCT 40/10/12.5

[152] Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide *[GRP-23701]*

omit from the column headed "Brand": Olmekar HCT 20/5/12.5

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[153] Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide *[GRP-23703]*

omit from the column headed "Brand": Olmekar HCT 40/5/12.5

[154] Schedule 5, entry for Olmesartan with amlodipine and hydrochlorothiazide *[GRP-23710]*

omit from the column headed "Brand": Olmekar HCT 40/10/25

[155] Schedule 5, after entry for Olmesartan with hydrochlorothiazide *[GRP-21161]*

insert:

Omalizumab	GRP-29930	Injection 75 mg in 0.5 mL single dose pre-filled pen	Injection	Xolair
Omalizumab	GRP-29930	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection	Omlyclo Xolair
Omalizumab	GRP-29934	Injection 150 mg in 1 mL single dose pre-filled pen	Injection	Xolair
Omalizumab	GRP-29934	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection	Omlyclo

[156] Schedule 5, entry for Paroxetine

omit from the column headed "Brand": Noumed Paroxetine

[157] Schedule 5, entry for Rivaroxaban *[GRP-29164]*

insert in the column headed "Brand" after entry for the Brand "iXarola": Relaban

[158] Schedule 5, entry for Rivaroxaban *[GRP-29173]*

insert in the column headed "Brand" after entry for the Brand "iXarola": Relaban

[159] Schedule 5, entry for Rizatripatan in the form Tablet (orally disintegrating) 10 mg (as benzoate)

insert in the column headed "Brand" after entry for the Brand "RIXALT": Rizatriptan-Au

[160] Schedule 5, entry for Tenofovir in the form Tablet containing tenofovir disoproxil fumarate 300 mg

omit from the column headed "Brand": Tenofovir APOTEX

[161] Schedule 5, entries for Tenofovir with emtricitabine

omit:

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Tenofovir with emtricitabine	GRP-21638	Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A)	Oral	Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA)

[162] Schedule 5, after entry for Ursodeoxycholic acid in the form Tablet 500 mg

insert:

Ustekinumab	GRP-29946	Solution for I.V. infusion 130 mg in 26 mL	Injection	Stelara Steqeyma
Ustekinumab	GRP-29948	Injection 90 mg in 1 mL single use pre-filled syringe	Injection	Stelara Steqeyma

[163] Schedule 5, entries for Varenicline

insert in the column headed "Brand" after entry for the Brand "VARENAPIX" (all instances): Varenicline Lupin

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