



PB 78 of 2022

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2022 (No. 9)

National Health Act 1953

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

Dated 25 August 2022

NIKOLAI TSYGANOV
Assistant Secretary (Acting)
Pricing and PBS Policy Branch
Technology Assessment and Access Division

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1 Name of Instrument

- (1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2022 (No. 9)*.
- (2) This instrument may also be cited as PB 78 of 2022.

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. <i>The whole of this instrument</i>	<i>1 September 2022</i>	<i>1 September 2022</i>

Note: This table relates only to the provisions of this instrument as originally made.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 Schedule

Schedule 1 to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 - Amendments

National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (PB 71 of 2012)

- [1] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 20 mg in 0.4 mL pre-filled syringe**
omit from the column headed "Responsible Person": **TX** substitute: **XT**
- [2] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen**
omit from the column headed "Responsible Person" for the brand "Amgevita" (all instances): **TX** substitute: **XT**
- [3] **Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe**
omit from the column headed "Responsible Person" for the brand "Amgevita" (all instances): **TX** substitute: **XT**
- [4] **Schedule 1, Part 1, entry for Alirocumab in each of the forms: Injection 75 mg in 1 mL single use pre-filled pen; and Injection 150 mg in 1 mL single use pre-filled pen**
omit from the column headed "Circumstances": **C12055**
- [5] **Schedule 1, Part 1, entry for Apremilast in each of the forms: Pack containing 4 tablets 10 mg, 4 tablets 20 mg and 19 tablets 30 mg; and Tablet 30 mg**
omit from the column headed "Circumstances": **C11115** substitute: **C13243**
- [6] **Schedule 1, Part 1, entry for Bortezomib in the form Powder for injection 3.5 mg**
insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	Bortezomib-AFT	AE	MP	C11099	See Note 3	See Note 3	1	D(100)
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- [7] **Schedule 1, Part 1, entry for Brentuximab vedotin**
omit from the column headed "Circumstances": **C8722 C8736 C10519 C10524 C10811 C10902 C12085 C12087 C12088 C12141 C13179 C13181 C13182 C13208 C13209 C13212 C13231 C13259 C13261** substitute: **C13134**
- [8] **Schedule 1, Part 1, entry for Cabazitaxel in the form Concentrated injection 60 mg in 1.5 mL, with diluent**
omit from the column headed "Circumstances" (all instances): **C4662** substitute: **C13207**
- [9] **Schedule 1, Part 1, after entry for Cabazitaxel in the form Concentrated injection 60 mg in 1.5 mL, with diluent**
insert:

	Solution concentrate for I.V. infusion 60 mg in 3 mL	Injection	Cabazitaxel Accord	OC	MP	C13207	See Note 3	See Note 3	1	D(100)
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[10] **Schedule 1, Part 1, entry for Cabazitaxel in the form Solution concentrate for I.V. infusion 60 mg in 6 mL**

omit from the column headed "Circumstances": C4662 substitute: C13207

[11] **Schedule 1, Part 1, entry for Cefazolin in the form Powder for injection 2 g (as sodium)**

(a) *insert in the column headed "Schedule Equivalent" for the brand "Cephazolin Alphapharm": a*

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

	a	Cefazolin-AFT	AE	MP	NP	C5826 C5867 C5881 C5890	10	0	5	
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[12] **Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 10 mg [Maximum Quantity: 120; Number of Repeats: 5]**

(a) *omit from the column headed "Purposes": P6676*

(b) *omit from the column headed "Purposes": P9763*

(c) *insert in numerical order in the column headed "Purposes": P13122 P13168*

(d) *omit from the column headed "Maximum Quantity": CN6676*

(e) *omit from the column headed "Maximum Quantity": CN9763*

(f) *insert in numerical order in the column headed "Maximum Quantity": CN13122 CN13168*

(g) *omit from the column headed "Number of Repeats": CN6676*

(h) *omit from the column headed "Number of Repeats": CN9763*

(i) *insert in numerical order in the column headed "Number of Repeats": CN13122 CN13168*

[13] **Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 25 mg**

substitute:

Capsule 25 mg	Oral	a	APO-Ciclosporin	TX	MP		60	3	30	
		a	Cyclosporin Sandoz	SZ	MP		60	3	30	
		a	Neoral 25	NV	MP		60	3	30	
		a	APO-Ciclosporin	TX	MP	P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168	120	5	30	C(100)
							CN6631	CN6631		
							CN6638	CN6638		
							CN6643	CN6643		
							CN6660	CN6660		
							CN9694	CN9694		
							CN9695	CN9695		
							CN9742	CN9742		

							CN9764 CN13122 CN13168	CN9764 CN13122 CN13168			
a	Cyclosporin Sandoz	SZ	MP			P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168	120 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168	5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168	30		C(100)
a	Neoral 25		NV	MP		P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168	120 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168	5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168	30		C(100)

[14] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 50 mg

substitute:

	Capsule 50 mg		Oral								
a	APO-Ciclosporin		TX	MP					60	3	30
a	Cyclosporin Sandoz	SZ	MP						60	3	30
a	Neoral 50		NV	MP					60	3	30
a	APO-Ciclosporin		TX	MP		P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168	120 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168	5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168	30		C(100)
a	Cyclosporin Sandoz	SZ	MP			P6631 P6638	120	5	30		C(100)

P6643 P6660 CN6631 CN6631
 P9694 P9695 CN6638 CN6638
 P9742 P9764 CN6643 CN6643
 P13122 P13168 CN6660 CN6660
 CN9694 CN9694
 CN9695 CN9695
 CN9742 CN9742
 CN9764 CN9764
 CN13122 CN13122
 CN13168 CN13168

a Neoral 50 NV MP

P6631 P6638 120 5 30 C(100)
 P6643 P6660 CN6631 CN6631
 P9694 P9695 CN6638 CN6638
 P9742 P9764 CN6643 CN6643
 P13122 P13168 CN6660 CN6660
 CN9694 CN9694
 CN9695 CN9695
 CN9742 CN9742
 CN9764 CN9764
 CN13122 CN13122
 CN13168 CN13168

[15] Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 100 mg

substitute:

Capsule 100 mg

Oral

a APO-Ciclosporin TX MP
 a Cyclosporin Sandoz SZ MP
 a Neoral 100 NV MP
 a APO-Ciclosporin TX MP

60 3 30
 60 3 30
 60 3 30
 P6631 P6638 120 5 30 C(100)
 P6643 P6660 CN6631 CN6631
 P9694 P9695 CN6638 CN6638
 P9742 P9764 CN6643 CN6643
 P13122 P13168 CN6660 CN6660
 CN9694 CN9694
 CN9695 CN9695
 CN9742 CN9742
 CN9764 CN9764
 CN13122 CN13122
 CN13168 CN13168

a Cyclosporin Sandoz SZ MP

P6631 P6638 120 5 30 C(100)
 P6643 P6660 CN6631 CN6631
 P9694 P9695 CN6638 CN6638
 P9742 P9764 CN6643 CN6643
 P13122 P13168 CN6660 CN6660
 CN9694 CN9694

[21] Schedule 1, Part 1, omit entry for Eptifibatide

[22] Schedule 1, Part 1, after entry for Gentamicin in the form Injection 80 mg (as sulfate) in 2 mL

insert:

Gilteritinib	Tablet 40 mg (as fumarate)	Oral	Xospata	LL	MP	C13166 C13167 P13166	84	0	84
					MP	C13166 C13167 P13167 P13242	84	4	84

[23] Schedule 1, Part 1, entry for Glatiramer

insert as first entry:

	Injection containing glatiramer acetate 40 mg in 1 mL single dose pre-filled pen	Injection	a	Copaxone	TB	MP	C6860 C7695	12	5	12
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[24] Schedule 1, Part 1, entry for Gliclazide in the form Tablet 60 mg (modified release)

omit from the column headed "Responsible Person" for the brand "ARDIX GLICLAZIDE 60mg MR": **RX**

substitute: **XT**

[25] Schedule 1, Part 1, entry for Glimepiride in the form Tablet 2 mg

omit:

			a	Dimirel	AV	MP NP		30	5	30
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[26] Schedule 1, Part 1, entry for Hydroxycarbamide

omit from the column headed "Responsible Person" for the brand "Hydrea": **BQ** substitute: **LM**

[27] Schedule 1, Part 1, entry for Icatibant

(a) insert in the column headed "Schedule Equivalent" for the brand "Cipla Icatibant": **a**

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

			a	Fyzant	JU	MP	C7273 C7274	1	1	1
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[28] Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) [Brand: Imatinib GH; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed "Circumstances": **C9208**

(b) insert in numerical order in the column headed "Circumstances": **C13132**

(c) omit from the column headed "Purposes": **P9208**

(d) insert in numerical order in the column headed "Purposes": **P13132**

- [29] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) [Brand: Imatinib-APOTEX; Maximum Quantity: 60; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances": C9208*
 - (b) *insert in numerical order in the column headed "Circumstances": C13132*
 - (c) *omit from the column headed "Purposes": P9208*
 - (d) *insert in numerical order in the column headed "Purposes": P13132*
- [30] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) [Brand: IMATINIB-DRLA; Maximum Quantity: 60; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances": C9208*
 - (b) *insert in numerical order in the column headed "Circumstances": C13132*
 - (c) *omit from the column headed "Purposes": P9208*
 - (d) *insert in numerical order in the column headed "Purposes": P13132*
- [31] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) [Brand: Imatinib GH; Maximum Quantity: 60; Number of Repeats: 5]**
- (a) *omit from the column headed "Circumstances": C9208*
 - (b) *insert in numerical order in the column headed "Circumstances": C13132*
- [32] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) [Brand: Imatinib-APOTEX; Maximum Quantity: 60; Number of Repeats: 5]**
- (a) *omit from the column headed "Circumstances": C9208*
 - (b) *insert in numerical order in the column headed "Circumstances": C13132*
- [33] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) [Brand: IMATINIB-DRLA;Maximum Quantity: 60; Number of Repeats: 5]**
- (a) *omit from the column headed "Circumstances": C9208*
 - (b) *insert in numerical order in the column headed "Circumstances": C13132*
- [34] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) [Brand: Imatinib GH; Maximum Quantity: 30; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances": C9208*
 - (b) *insert in numerical order in the column headed "Circumstances": C13132*
 - (c) *omit from the column headed "Purposes": P9208*
 - (d) *insert in numerical order in the column headed "Purposes": P13132*

- [35] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) [Brand: Imatinib-APOTEX; Maximum Quantity: 30; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances": C9208*
 - (b) *insert in numerical order in the column headed "Circumstances": C13132*
 - (c) *omit from the column headed "Purposes": P9208*
 - (d) *insert in numerical order in the column headed "Purposes": P13132*
- [36] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) [Brand: IMATINIB-DRLA; Maximum Quantity: 30; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances": C9208*
 - (b) *insert in numerical order in the column headed "Circumstances": C13132*
 - (c) *omit from the column headed "Purposes": P9208*
 - (d) *insert in numerical order in the column headed "Purposes": P13132*
- [37] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) [Brand: Imatinib GH; Maximum Quantity: 30; Number of Repeats: 5]**
- (a) *omit from the column headed "Circumstances": C9208*
 - (b) *insert in numerical order in the column headed "Circumstances": C13132*
- [38] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) [Brand: Imatinib-APOTEX; Maximum Quantity: 30; Number of Repeats: 5]**
- (a) *omit from the column headed "Circumstances": C9208*
 - (b) *insert in numerical order in the column headed "Circumstances": C13132*
- [39] **Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) [Brand: IMATINIB-DRLA; Maximum Quantity: 30; Number of Repeats: 5]**
- (a) *omit from the column headed "Circumstances": C9208*
 - (b) *insert in numerical order in the column headed "Circumstances": C13132*
- [40] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate) [Maximum Quantity: 60; Number of Repeats: 2]**
- (a) *omit from the column headed "Circumstances" (all instances): C9208*
 - (b) *insert in numerical order in the column headed "Circumstances": C13132*
 - (c) *omit from the column headed "Purposes" (all instances): P9208*
 - (d) *insert in numerical order in the column headed "Purposes": P13132*

- [41] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate) [Maximum Quantity: 60; Number of Repeats: 5]**
 (a) *omit from the column headed "Circumstances" (all instances): C9208*
 (b) *insert in numerical order in the column headed "Circumstances": C13132*
- [42] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) [Maximum Quantity: 30; Number of Repeats: 2]**
 (a) *omit from the column headed "Circumstances" (all instances): C9208*
 (b) *insert in numerical order in the column headed "Circumstances": C13132*
 (c) *omit from the column headed "Purposes" (all instances): P9208*
 (d) *insert in numerical order in the column headed "Purposes": P13132*
- [43] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) [Maximum Quantity: 30; Number of Repeats: 5]**
 (a) *omit from the column headed "Circumstances" (all instances): C9208*
 (b) *insert in numerical order in the column headed "Circumstances": C13132*
- [44] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 600 mg (as mesilate) [Maximum Quantity: 30; Number of Repeats: 2]**
 (a) *omit from the column headed "Circumstances": C9208*
 (b) *insert in numerical order in the column headed "Circumstances": C13132*
 (c) *omit from the column headed "Purposes": P9208*
 (d) *insert in numerical order in the column headed "Purposes": P13132*
- [45] **Schedule 1, Part 1, entry for Imatinib in the form Tablet 600 mg (as mesilate) [Maximum Quantity: 30; Number of Repeats: 5]**
 (a) *omit from the column headed "Circumstances": C9208*
 (b) *insert in numerical order in the column headed "Circumstances": C13132*
- [46] **Schedule 1, Part 1, entry for Leflunomide in the form Tablet 20 mg**
omit:

	a	Arabloc	AV	MP	C5681 C5766	30	5	30
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- [47] **Schedule 1, Part 1, entry for Molnupiravir**
omit from the column headed "Circumstances": C13107 C13108 C13110 C13112 *substitute: C13155 C13156 C13201 C13224*

- [48] **Schedule 1, Part 1, after entry for Nintedanib in the form Capsule 150 mg**
insert:

Niraparib	Capsule 100 mg (as tosilate monohydrate)	Oral	Zejula	GK	MP	C-13202 C-13204 C-13264 C-13273	P13202	56	2	56
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	MP	C13202 C13204 C13264 C13273	P13264	56	5	56
	MP	C13202 C13204 C13264 C13273	P13273	84	2	84
	MP	C13202 C13204 C13264 C13273	P13204	84	5	84

- [49] **Schedule 1, Part 1, entry for Nirmatrelvir and ritonavir**
omit from the column headed "Circumstances": C13107 C13108 C13110 C13112 substitute: C13155 C13156 C13201 C13224
- [50] **Schedule 1, Part 1, omit entry for Norethisterone with mestranol**
- [51] **Schedule 1, Part 1, entry for Olaparib in the form Tablet 100 mg [Maximum Quantity: 112; Number of Repeats: 2]**
 (a) *omit from the column headed "Circumstances": C10914*
 (b) *insert in numerical order in the column headed "Circumstances": C13226*
 (c) *omit from the column headed "Purposes": P10914*
 (d) *insert in numerical order in the column headed "Purposes": P13226*
- [52] **Schedule 1, Part 1, entry for Olaparib in the form Tablet 100 mg [Maximum Quantity: 112; Number of Repeats: 5]**
 (a) *omit from the column headed "Circumstances": C10914*
 (b) *insert in numerical order in the column headed "Circumstances": C13226*
- [53] **Schedule 1, Part 1, entry for Olaparib in the form Tablet 150 mg [Maximum Quantity: 112; Number of Repeats: 2]**
 (a) *omit from the column headed "Circumstances": C10914*
 (b) *insert in numerical order in the column headed "Circumstances": C13226*
 (c) *omit from the column headed "Purposes": P10914*
 (d) *insert in numerical order in the column headed "Purposes": P13226*
- [54] **Schedule 1, Part 1, entry for Olaparib in the form Tablet 150 mg [Maximum Quantity: 112; Number of Repeats: 5]**
 (a) *omit from the column headed "Circumstances": C10914*
 (b) *insert in numerical order in the column headed "Circumstances": C13226*
- [55] **Schedule 1, Part 1, after entry for Oxybutynin in the form Tablet containing oxybutynin hydrochloride 5 mg**
insert:

Tablet containing oxybutynin chloride 5 mg (s19A)	Oral	Oxybutynin Chloride (Novitium)	QY MP NP	C6241	100	5	100
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[56] Schedule 1, Part 1, entry for Pembrolizumab

- (a) omit from the column headed "Circumstances": **C9863 C9864**
- (b) omit from the column headed "Circumstances": **C10679**
- (c) omit from the column headed "Circumstances": **C10702**
- (d) omit from the column headed "Circumstances": **C11993**
- (e) insert in numerical order in the column headed "Circumstances": **C13126 C13213 C13214 C13245**

[57] Schedule 1, Part 1, entry for Pemetrexed in each of the forms: Powder for I.V. infusion 100 mg (as disodium); and Powder for I.V. infusion 500 mg (as disodium)

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

	Pemetrexed-AFT	AE	MP					See Note 3	See Note 3	1	D(100)
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[58] Schedule 1, Part 1, after entry for Polyethylene glycol 400 with propylene glycol in the form Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28

insert:

	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 30	Application to the eye	Systane	AQ	AO	MP	NP	C6172	2	5	1	
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[59] Schedule 1, Part 1, entry for Rituximab

substitute:

Rituximab	Solution for I.V. infusion 100 mg in 10 mL	Injection	a	Ruxience	PF	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
			a	Riximyo	SZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	D(100)
			a	Truxima	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	2	D(100)
	Solution for I.V. infusion 500 mg in 50 mL	Injection	a	Riximyo	SZ	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
			a	Ruxience	PF	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)
			a	Truxima	EW	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

- [60] **Schedule 1, Part 1, entry for Ruxolitinib in the form Tablet 5 mg [Maximum Quantity: 112; Number of Repeats: 0]**
 (a) *omit from the column headed "Circumstances": C5917 C5920 C11225 C11226 substitute: C13127 C13128 C13130 C13173*
 (b) *omit from the column headed "Purposes": P11225 P11226 substitute: P13127 P13173*
- [61] **Schedule 1, Part 1, entry for Ruxolitinib in the form Tablet 5 mg [Maximum Quantity: 112; Number of Repeats: 5]**
 (a) *omit from the column headed "Circumstances": C5917 C5920 C11225 C11226 substitute: C13127 C13128 C13130 C13173*
 (b) *omit from the column headed "Purposes": P5917 P5920 substitute: P13128 P13130*
- [62] **Schedule 1, Part 1, entry for Ruxolitinib in the form Tablet 10 mg [Maximum Quantity: 56; Number of Repeats: 0]**
 (a) *omit from the column headed "Circumstances": C5917 C5920 C11225 C11226 substitute: C13127 C13128 C13130 C13173*
 (b) *omit from the column headed "Purposes": P11225 P11226 substitute: P13127 P13173*
- [63] **Schedule 1, Part 1, entry for Ruxolitinib in the form Tablet 10 mg [Maximum Quantity: 56; Number of Repeats: 5]**
 (a) *omit from the column headed "Circumstances": C5917 C5920 C11225 C11226 substitute: C13127 C13128 C13130 C13173*
 (b) *omit from the column headed "Purposes": P5917 P5920 substitute: P13128 P13130*
- [64] **Schedule 1, Part 1, entry for Ruxolitinib in the form Tablet 15 mg [Maximum Quantity: 56; Number of Repeats: 0]**
 (a) *omit from the column headed "Circumstances": C5917 C5920 C11225 C11226 substitute: C13127 C13128 C13130 C13173*
 (b) *omit from the column headed "Purposes": P11225 P11226 substitute: P13127 P13173*
- [65] **Schedule 1, Part 1, entry for Ruxolitinib in the form Tablet 15 mg [Maximum Quantity: 56; Number of Repeats: 5]**
 (a) *omit from the column headed "Circumstances": C5917 C5920 C11225 C11226 substitute: C13127 C13128 C13130 C13173*
 (b) *omit from the column headed "Purposes": P5917 P5920 substitute: P13128 P13130*
- [66] **Schedule 1, Part 1, entry for Ruxolitinib in the form Tablet 20 mg [Maximum Quantity: 56; Number of Repeats: 0]**
 (a) *omit from the column headed "Circumstances": C5917 C5920 C11225 C11226 substitute: C13127 C13128 C13130 C13173*
 (b) *omit from the column headed "Purposes": P11225 P11226 substitute: P13127 P13173*
- [67] **Schedule 1, Part 1, entry for Ruxolitinib in the form Tablet 20 mg [Maximum Quantity: 56; Number of Repeats: 5]**
 (a) *omit from the column headed "Circumstances": C5917 C5920 C11225 C11226 substitute: C13127 C13128 C13130 C13173*
 (b) *omit from the column headed "Purposes": P5917 P5920 substitute: P13128 P13130*
- [68] **Schedule 1, Part 1, after entry for Selexipag in the form Tablet 1.6 mg**

insert:

Selinexor	Tablet 20 mg	Oral	Xpovio	TG MP	C13115 C13116 C13118 C13159 C13160 C13161 C13228 C13229	P13115 P13229 P13256	16	2	16	D(100)
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							C13256						
					MP		C13115 C13116 C13118 C13159 C13160 C13161 C13228 C13229 C13256	P13116 P13118 P13228	20	2	20		D(100)
					MP		C13115 C13116 C13118 C13159 C13160 C13161 C13228 C13229 C13256	P13159 P13160 P13161	32	2	32		D(100)

[69] Schedule 1, Part 1, entry for Siltuximab in each of the forms: Powder for injection 100 mg; and Powder for injection 400 mg

omit from the column headed "Responsible Person": EY substitute: RJ

[70] Schedule 1, Part 1, entry for Sonidegib in the form Capsule 200 mg

(a) omit from the column headed "Circumstances": C7540 C7557

(b) insert in numerical order in the column headed "Circumstances": C13175 C13260

[71] Schedule 1, Part 1, entry for Sunitinib

substitute:

Sunitinib	Capsule 12.5 mg	Oral	a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11878 P13152 P13153	28	1	28		
			a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11878 P13152 P13153	28	1	28		
			a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P4862	28	2	28		
			a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P4862	28	2	28		
			a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11875	28	3	28		
			a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11875	28	3	28		

	a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P7471	28	5	28
	a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P7471	28	5	28
Capsule 25 mg		Oral							
	a	ARX-Sunitinib	XT	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11878 P13152 P13153	28	1	28
	a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11878 P13152 P13153	28	1	28
	a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11878 P13152 P13153	28	1	28
	a	ARX-Sunitinib	XT	MP	C4862 C7471 C11875 C11878 C13152 C13153	P4862	28	2	28
	a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P4862	28	2	28
	a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P4862	28	2	28
	a	ARX-Sunitinib	XT	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11875	28	3	28
	a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11875	28	3	28
	a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11875	28	3	28
	a	ARX-Sunitinib	XT	MP	C4862 C7471 C11875 C11878 C13152 C13153	P7471	28	5	28
	a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P7471	28	5	28

	a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P7471	28	5	28
Capsule 37.5 mg		Oral							
	a	ARX-Sunitinib	XT	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11878 P13152 P13153	28	1	28
	a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11878 P13152 P13153	28	1	28
	a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11878 P13152 P13153	28	1	28
	a	ARX-Sunitinib	XT	MP	C4862 C7471 C11875 C11878 C13152 C13153	P4862	28	2	28
	a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P4862	28	2	28
	a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P4862	28	2	28
	a	ARX-Sunitinib	XT	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11875	28	3	28
	a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11875	28	3	28
	a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11875	28	3	28
	a	ARX-Sunitinib	XT	MP	C4862 C7471 C11875 C11878 C13152 C13153	P7471	28	5	28
	a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P7471	28	5	28
	a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P7471	28	5	28

Capsule 50 mg	Oral	a	ARX-Sunitinib	XT	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11878 P13152 P13153	28	1	28
		a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11878 P13152 P13153	28	1	28
		a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11878 P13152 P13153	28	1	28
		a	ARX-Sunitinib	XT	MP	C4862 C7471 C11875 C11878 C13152 C13153	P4862	28	2	28
		a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P4862	28	2	28
		a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P4862	28	2	28
		a	ARX-Sunitinib	XT	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11875	28	3	28
		a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11875	28	3	28
		a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P11875	28	3	28
		a	ARX-Sunitinib	XT	MP	C4862 C7471 C11875 C11878 C13152 C13153	P7471	28	5	28
		a	Sunitinib Sandoz	SZ	MP	C4862 C7471 C11875 C11878 C13152 C13153	P7471	28	5	28
		a	Sutent	PF	MP	C4862 C7471 C11875 C11878 C13152 C13153	P7471	28	5	28

[72] Schedule 1, Part 1, after entry for Triglycerides, medium chain in the form Oral liquid 225 mL, 15 (betaquik)

insert:

Instrument Number PB 78 of 2022

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Oral liquid 225 mL, 15 (K.Quik)	Oral	K.Quik	VF	MP NP	C6147 C6191	2	5	1
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[73] **Schedule 1, Part 1, entry for Valganciclovir in the form Powder for oral solution 50 mg (as hydrochloride) per mL, 100 mL**

omit from the column headed "Responsible Person": RO substitute: PB

[74] **Schedule 1, Part 1, entry for Vedolizumab in the form Injection 108 mg in 0.68 mL single use pre-filled pen [Maximum Quantity: 2; Number of Repeats: 0]**

- (a) *omit from the column headed "Circumstances": C12077*
- (b) *omit from the column headed "Circumstances": C12218*
- (c) *omit from the column headed "Circumstances": C12244 C12250*
- (d) *insert in numerical order in the column headed "Circumstances": C13236 C13237*
- (e) *omit from the column headed "Purposes": P12218*
- (f) *omit from the column headed "Purposes": P12250*
- (g) *insert in numerical order in the column headed "Purposes": P13236 P13237*

[75] **Schedule 1, Part 1, entry for Vedolizumab in the form Injection 108 mg in 0.68 mL single use pre-filled pen [Maximum Quantity: 2; Number of Repeats: 5]**

- (a) *omit from the column headed "Circumstances": C12077*
- (b) *omit from the column headed "Circumstances": C12218*
- (c) *omit from the column headed "Circumstances": C12244 C12250*
- (d) *insert in numerical order in the column headed "Circumstances": C13236 C13237*
- (e) *omit from the column headed "Purposes": P12077*
- (f) *omit from the column headed "Purposes": P12244*

[76] **Schedule 1, Part 1, entry for Venetoclax in the form Tablet 10 mg**

substitute:

Tablet 10 mg	Oral	Venclexta	VE	MP	C10995	14	0	2
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[77] **Schedule 1, Part 1, entry for Vismodegib**

- (a) *omit from the column headed "Circumstances": C7540 C7557*
- (b) *insert in numerical order in the column headed "Circumstances": C13175 C13268*

[78] **Schedule 1, Part 1, entry for Vorinostat in the form Capsule 100 mg [Maximum Quantity: 120; Number of Repeats: 1]**

- (a) *omit from the column headed "Circumstances": C6957 C6964 substitute: C13177 C13246*
- (b) *omit from the column headed "Purposes": P6964 substitute: P13246*

[79] Schedule 1, Part 1, entry for Vorinostat in the form Capsule 100 mg [Maximum Quantity: 120; Number of Repeats: 2]

(a) omit from the column headed "Circumstances": **C6957 C6964** substitute: **C13177 C13246**

(b) omit from the column headed "Purposes": **P6957** substitute: **P13177**

[80] Schedule 1, Part 2, after entry for Nifedipine

insert:

Norethisterone with mestranol	Pack containing 21 tablets 1 mg- Oral 50 micrograms and 7 inert tablets	Norinyl-1/28	PF	MP	NP	4	2	4
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[81] Schedule 1, Part 2, after entry for Pancreatic extract

insert:

Rituximab	Solution for I.V. infusion 100 mg in 10 mL	Injection	Ruxience	PF	MP	C7399 C7400 C9451 C9542 C10227	See Note 3	See Note 3	1	D(100)	
			Riximyo	SZ	MP	C7399 C7400 C9451 C9542 C10227	See Note 3	See Note 3	2	D(100)	
			Truxima	EW	MP	C7399 C7400 C9451 C9542 C10227	See Note 3	See Note 3	2	D(100)	
	Solution for I.V. infusion 500 mg in 50 mL	Injection	a	Riximyo	SZ	MP	C9446 C9611	2	1	1	D(100)
			a	Ruxience	PF	MP	C9446 C9611	2	1	1	D(100)
			a	Truxima	EW	MP	C9446 C9611	2	1	1	D(100)
				Riximyo	SZ	MP	C7399 C7400 C9451 C9542 C10227	See Note 3	See Note 3	1	D(100)
				Ruxience	PF	MP	C7399 C7400 C9451 C9542 C10227	See Note 3	See Note 3	1	D(100)
				Truxima	EW	MP	C7399 C7400 C9451 C9542 C10227	See Note 3	See Note 3	1	D(100)

[82] Schedule 1, Part 2, omit entry for Rivaroxaban

[83] Schedule 3,

omit:

EY	EUSA Pharma (Australia) Pty Ltd	14 646 058 728
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[84] Schedule 3, after details relevant for Responsible Person code TD

insert:

TG	ANTENGENE (AUS) PTY. LTD.	30 638 038 990
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[85] Schedule 4, Part 1, entry for Alirocumab

omit:

	C12055		<p>Familial heterozygous hypercholesterolaemia Grandfather treatment Patient must have received non-PBS subsidised treatment with this drug for this PBS indication prior to 1 August 2021; AND The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6 prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had an LDL cholesterol level in excess of 2.6 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS-subsidised treatment with this drug for this condition was initiated; OR Patient must have had an LDL cholesterol level in excess of 5 millimoles per litre at the time non-PBS-subsidised treatment with this drug for this condition was initiated; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must not be receiving concomitant PBS-subsidised treatment with another drug that belongs to the same pharmacological class as this drug, for this PBS indication. Must be treated by a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)).</p>	Compliance with Authority Required procedures
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			<p>The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated.</p> <p>A clinically important product-related adverse event is defined as follows:</p> <p>(i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or</p> <p>(ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or</p> <p>(iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.</p> <p>If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retreatment should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retreatment should not have occurred until CK had returned to normal.</p> <p>In the event of a trial of the alternative statin, the dose of the alternative statin should have been increased not more often than every 4 weeks until the maximum tolerated dose was reached or target LDL-c had been achieved.</p> <p>The following must be stated at the time of application and documented in the patient's medical records:</p> <p>(i) the qualifying Dutch Lipid Clinic Network Score; or</p> <p>(ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia</p> <p>One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment:</p> <p>(i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or</p> <p>(ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or</p> <p>(iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only.</p> <p>For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.</p>	
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[86] Schedule 4, Part 1, entry for Apremilast

substitute:

Apremilast	C13243		<p>Severe chronic plaque psoriasis</p> <p>Patient must have failed to achieve an adequate response after at least 6 weeks of treatment with methotrexate prior to initiating treatment with this drug; OR</p> <p>Patient must have a contraindication to methotrexate according to the Therapeutic Goods Administration (TGA) approved Product Information; OR</p> <p>Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; AND</p> <p>The condition must have caused significant interference with quality of life; AND</p> <p>Patient must not be undergoing concurrent PBS-subsidised treatment for psoriasis with each of: (i) a biological medicine, (ii) ciclosporin.</p> <p>Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist; OR</p> <p>Must be treated by a general practitioner who has been directed to continue treatment (not initiate treatment) by one of the above practitioner types.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13243
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				Patient must be at least 18 years of age.	
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[87] Schedule 4, Part 1, entry for Brentuximab vedotin

substitute:

Brentuximab vedotin	C13134			<p>CD30 positive peripheral T-cell lymphoma, non-cutaneous type</p> <p>Initial treatment</p> <p>Patient must have histological confirmation of CD30 expression in at least 3% of malignant cells; AND</p> <p>The treatment must be for first line therapy for this condition; AND</p> <p>The treatment must be for curative intent; AND</p> <p>The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone; AND</p> <p>The treatment must not be more than 6 treatment cycles under this restriction in a lifetime.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(a) details (date, unique identifying number/code or provider number) of a histology report on the tumour sample from an Approved Pathology Authority showing CD30 positivity of at least 3% malignant cells; and</p> <p>(b) The date of initial diagnosis of Peripheral T-cell lymphoma.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Written Authority Required procedures
	C13179			<p>CD30 positive cutaneous T-cell lymphoma</p> <p>Initial treatment</p> <p>Patient must have pathologically confirmed CD30 positive cutaneous T-cell lymphoma; AND</p> <p>Patient must have CD30 positivity of at least 3% of malignant cells; AND</p> <p>Patient must have a diagnosis of mycosis fungoides; OR</p> <p>Patient must have a diagnosis of Sezary syndrome; OR</p> <p>Patient must have a diagnosis of primary cutaneous anaplastic large cell lymphoma; AND</p> <p>Patient must have received prior systemic treatment for this condition; AND</p> <p>The condition must be relapsed or refractory; AND</p> <p>The treatment must not exceed 4 cycles under this restriction in a lifetime; AND</p> <p>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(a) details (date, unique identifying number/code or provider number) of the histopathology report from an Approved Pathology Authority demonstrating the patient has a diagnosis of either mycosis fungoides, Sezary syndrome or primary cutaneous anaplastic large cell lymphoma; and</p> <p>(b) details (date, unique identifying number/code or provider number) of a histology report on the tumour sample or of a flow cytometric analysis of lymphoma cells of the blood showing CD30 positivity of at least 3% of malignant cells; and</p> <p>(c) Date of commencement and completion of the most recent prior systemic treatment.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Written Authority Required procedures
	C13181			<p>CD30 positive cutaneous T-cell lymphoma</p> <p>Continuing treatment</p>	Compliance with Authority Required

			<p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have achieved an objective response with this drug; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The treatment must not exceed 12 cycles under this restriction in a lifetime. An objective response is defined as the demonstration of response by clinical observation of skin lesions, or response by positron-emission tomography (PET) and/or computed tomography (CT) standard criteria.</p>	procedures
	C13182		<p>CD30 positive systemic anaplastic large cell lymphoma Initial treatment The treatment must be for curative intent; AND Patient must have undergone appropriate prior front-line curative intent chemotherapy; AND Patient must demonstrate relapsed or chemotherapy-refractory disease; AND Patient must have responded to PBS-subsidised treatment with this drug if previously used for initial treatment of CD30 positive peripheral T-cell lymphoma, non-cutaneous type; AND The treatment must not exceed 4 cycles under this restriction. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number or provider number) of a histology report showing evidence of the tumour's CD30 positivity; and (b) The date of initial diagnosis of systemic anaplastic large cell lymphoma; and (c) Dates of commencement and completion of front-line curative intent chemotherapy; and (d) a declaration of whether the patient's disease is relapsed or refractory, and the date and means by which the patient's disease was assessed as being relapsed or refractory. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Written Authority Required procedures
	C13208		<p>Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must have undergone a primary autologous stem cell transplant (ASCT) for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 12 cycles of treatment under this restriction. The treatment must not exceed a total of 16 cycles of combined initial and continuing treatment in a lifetime.</p>	Compliance with Authority Required procedures
	C13209		<p>Relapsed or Refractory Hodgkin lymphoma Initial treatment Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND Patient must not be suitable for ASCT for this condition; OR Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND Patient must have experienced a relapsed CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; OR Patient must have experienced a refractory CD30+ Hodgkin lymphoma following at least two prior treatments for this condition; AND Patient must not receive more than 4 cycles of treatment under this restriction. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time</p>	Compliance with Written Authority Required procedures

			assessment), or in writing via HPOS form upload or mail. If the application is submitted through HPOS upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
	C13212		CD30 positive peripheral T-cell lymphoma, non-cutaneous type Continuing treatment The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone; AND Patient must have completed 6 initial cycles of PBS-subsidised treatment with this drug for this indication; AND Patient must have achieved at least a partial response to the 6 initial cycles of treatment with a combination of this drug and cyclophosphamide, doxorubicin and prednisone for this indication; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not be more than 2 treatment cycles under this restriction in a lifetime. Partial response is defined using Lugano Response Criteria for Non-Hodgkin Lymphoma as: (a) Positron emission tomography-based response: lymph nodes and extralymphatic sites - a score of 4 (uptake moderately > liver), or 5 (uptake markedly higher than liver and/or new lesions), with reduced uptake compared with baseline and residual mass(es) of any size; nonmeasured lesions - not applicable; organ enlargement - not applicable; new lesions - none; bone marrow - residual uptake higher than uptake in normal marrow but reduced compared with baseline (diffuse uptake compatible with reactive changes from chemotherapy allowed). If there are persistent focal changes in the marrow in the context of a nodal response, consideration should be given to further evaluation with MRI or biopsy or an interval scan; OR (b) Computed tomography-based response: lymph nodes and extralymphatic sites - greater than or equal to 50% decrease in the sum of the product of the perpendicular diameters for multiple lesions, of up to six (6) target measurable nodes and extranodal sites; non-measured lesions - absent/normal, regressed but no increase; new lesions - none; bone marrow - not applicable.	Compliance with Authority Required procedures
	C13231		Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must not have undergone an autologous stem cell transplant (ASCT) for this condition; AND Patient must not be suitable for ASCT for this condition; OR Patient must not be suitable for treatment with multi-agent chemotherapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 12 cycles of treatment under this restriction. The treatment must not exceed a total of 16 cycles of combined initial and continuing treatment in a lifetime.	Compliance with Authority Required procedures
	C13259		Relapsed or Refractory Hodgkin lymphoma Initial treatment Patient must have undergone a primary autologous stem cell transplant (ASCT); AND Patient must have experienced a relapsed CD30+ Hodgkin lymphoma post ASCT; OR Patient must have experienced a refractory CD30+ Hodgkin lymphoma post ASCT; AND Patient must not receive more than 4 cycles of treatment under this restriction. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail. If the application is submitted through HPOS upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures

	C13261			CD30 positive systemic anaplastic large cell lymphoma Continuing treatment Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed 12 cycles under this restriction in a lifetime.	Compliance with Authority Required procedures
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[88] Schedule 4, Part 1, entry for Cabazitaxel

substitute:

Cabazitaxel	C13207			Castration resistant metastatic carcinoma of the prostate The treatment must be in combination with prednisone or prednisolone; AND The condition must be resistant to treatment with docetaxel; OR Patient must have a documented intolerance necessitating permanent treatment withdrawal or a contraindication to docetaxel; AND The treatment must not be used in combination with a novel hormonal drug; AND Patient must have a WHO performance status of 2 or less; AND Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel.	Compliance with Authority Required procedures - Streamlined Authority Code 13207
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[89] Schedule 4, Part 1, entry for Ciclosporin

(a) *omit:*

		P6676	CN6676	Severe psoriasis Management (initiation, stabilisation and review of therapy) The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life. Must be treated by a dermatologist.	Compliance with Authority Required procedures - Streamlined Authority Code 6676
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(b) *omit:*

		P9763	CN9763	Severe psoriasis Management (initiation, stabilisation and review of therapy) The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life. Must be treated by a dermatologist.	Compliance with Authority Required procedures - Streamlined Authority Code 9763
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(c) *insert in numerical order after existing text:*

		P13122	CN13122	Severe psoriasis Management (initiation, stabilisation and review of therapy) The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist.	Compliance with Authority Required procedures - Streamlined Authority Code 13122
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		P13168	CN13168	<p>Severe psoriasis Management (initiation, stabilisation and review of therapy) The condition must be ineffective to other systemic therapies; OR The condition must be inappropriate for other systemic therapies; AND The condition must have caused significant interference with quality of life. Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) an accredited dermatology registrar in consultation with a dermatologist.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13168
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[90] Schedule 4, Part 1, entry for Crizotinib

substitute:

Crizotinib	C13186			<p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.</p>	Compliance with Authority Required procedures
	C13233			<p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND Patient must have a WHO performance status of 2 or less. Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be documented in the patient's medical records: (a) evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.</p>	Compliance with Authority Required procedures
	C13250			<p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND Patient must have a WHO performance status of 2 or less; AND Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing; AND Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and</p>	Compliance with Authority Required procedures

				(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be documented in the patient's medical records: (a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.	
	C13251			Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures

[91] Schedule 4, Part 1, entry for Dapagliflozin

insert in numerical order after existing text:

	C13230			Chronic kidney disease Patient must have a diagnosis of chronic kidney disease, defined as abnormalities of at least one of: (i) kidney structure, (ii) kidney function, present for at least 3 months, prior to initiating treatment with this drug; AND Patient must have an estimated glomerular filtration rate of between 25 to 75 mL/min/1.73 m ² inclusive prior to initiating treatment with this drug; AND Patient must have a urinary albumin to creatinine ratio of between 200 to 5000 mg/g (22.6-565 mg/mmol) inclusive prior to initiating treatment with this drug; AND Patient must discontinue treatment with this drug prior to initiating renal replacement therapy, defined as dialysis or kidney transplant; AND Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must be stabilised, for at least 4 weeks, on either: (i) an ACE inhibitor or (ii) an angiotensin II receptor antagonist, unless medically contraindicated, prior to initiation of combination therapy with this drug. Patients with polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; patients requiring or with a recent history of cytotoxic or immunosuppressive therapy for kidney disease; and patients with an organ transplant are not eligible for treatment with this drug.	Compliance with Authority Required procedures - Streamlined Authority Code 13230
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[92] Schedule 4, Part 1, entry for Dupilumab

omit entry for circumstances code "C12497" and substitute:

	C12497			Chronic severe atopic dermatitis Initial treatment of the whole body Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands; AND The treatment must be the sole PBS-subsidised biological medicine for this PBS indication; AND Patient must not have experienced an inadequate response to this biological medicine in this PBS indication. Must be treated by a dermatologist; OR	Compliance with Written Authority Required procedures
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				<p>Must be treated by a clinical immunologist. Patient must be 12 years of age or older. State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application. Acceptable scores can be: (a) current scores; or (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records. Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.</p>	
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[93] Schedule 4, Part 1, entry for Entrectinib

substitute:

Entrectinib	C13184			<p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND Patient must have a WHO performance status of 2 or less; AND Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition; OR Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal; AND Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The following must be documented in the patient's medical records: (a) evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material.</p>	Compliance with Authority Required procedures
	C13276			<p>Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Continuing treatment The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.</p>	Compliance with Authority Required procedures

[94] Schedule 4, Part 1, omit entry for Eptifibatid

[95] Schedule 4, Part 1, after entry for Gentamicin

insert:

Gilteritinib	C13166	P13166		<p>Relapsed or refractory Acute Myeloid Leukaemia Initial treatment</p>	Compliance with Authority Required
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			<p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>The condition must not be acute promyelocytic leukaemia; AND</p> <p>The condition must be internal tandem duplication (ITD) and/or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, confirmed through a pathology report from an Approved Pathology Authority; AND</p> <p>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 prior to treatment initiation.</p> <p>The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.</p>	procedures
	C13167	P13167	<p>Relapsed or refractory Acute Myeloid Leukaemia</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022; AND</p> <p>Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>The condition must have relapsed or been refractory prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND</p> <p>The condition must be internal tandem duplication (ITD) and/or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition, confirmed through a pathology report from an Approved Pathology Authority; AND</p> <p>The condition must not be acute promyelocytic leukaemia; AND</p> <p>Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated.</p> <p>Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.</p> <p>If abnormal blood counts suggest the potential for relapsed AML, following a response to gilteritinib, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.</p> <p>Progressive disease is defined as the presence of any of the following:</p> <ul style="list-style-type: none"> (a) Leukaemic cells in the CSF; or (b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or (c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or (d) Extramedullary leukaemia. <p>The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.</p>	Compliance with Authority Required procedures
	C13242	P13242	<p>Relapsed or refractory Acute Myeloid Leukaemia</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have developed disease progression while being treated with this drug for this condition; AND</p> <p>Patient must not be undergoing or have undergone a stem cell transplant.</p> <p>Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.</p> <p>If abnormal blood counts suggest the potential for relapsed AML, following a response to gilteritinib, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.</p> <p>Progressive disease is defined as the presence of any of the following:</p> <ul style="list-style-type: none"> (a) Leukaemic cells in the CSF; or (b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy; or (c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause; or 	Compliance with Authority Required procedures

				(d) Extramedullary leukaemia.	
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[96] Schedule 4, Part 1, entry for Imatinib

(a) omit:

	C9208	P9208		<p>Malignant gastrointestinal stromal tumour</p> <p>Continuing treatment</p> <p>The condition must be metastatic; OR</p> <p>The condition must be unresectable; AND</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be given at a dose not exceeding 600 mg per day.</p> <p>Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib</p> <p>Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.</p> <p>A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9208
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(b) insert in numerical order after existing text:

	C13132	P13132		<p>Malignant gastrointestinal stromal tumour</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be given at a dose not exceeding 600 mg per day.</p> <p>Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib</p> <p>Patients with metastatic/unresectable disease who achieve a response to treatment at an imatinib dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals. Patients who fail to achieve a response to 400 mg per day may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.</p> <p>A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50% or greater. (Response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80.)</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13132
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[97] Schedule 4, Part 1, entry for Molnupiravir

substitute:

Molnupiravir	C13155			<p>SARS-CoV-2 infection</p> <p>Patient must have received a positive polymerase chain reaction (PCR) test result; OR</p> <p>Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner; AND</p> <p>Patient must have at least one sign or symptom attributable to COVID-19; AND</p> <p>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND</p> <p>Patient must be moderately to severely immunocompromised; AND</p> <p>Patient must be at risk of progression to severe disease due to immunocompromised status; AND</p> <p>The treatment must be initiated within 5 days of symptom onset.</p> <p>Patient must be at least 18 years of age.</p> <p>For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with:</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13155
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			<p>1. Any primary or acquired immunodeficiency including:</p> <p>a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders,</p> <p>b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months),</p> <p>c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR</p> <p>2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received:</p> <p>a. Chemotherapy or whole body radiotherapy,</p> <p>b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy,</p> <p>c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin),</p> <p>d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR</p> <p>3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received rituximab; OR</p> <p>4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR</p> <p>5. People with disability with multiple comorbidities and/or frailty.</p> <p>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records</p> <p>For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.</p> <p>Access to this drug through this restriction is permitted irrespective of vaccination status.</p> <p>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</p> <p>Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p> <p>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p>	
	C13156		<p>SARS-CoV-2 infection</p> <p>Patient must have received a positive polymerase chain reaction (PCR) test result; OR</p> <p>Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner;</p> <p>AND</p> <p>Patient must have at least one sign or symptom attributable to COVID-19; AND</p> <p>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND</p> <p>The treatment must be initiated within 5 days of symptom onset.</p> <p>Patient must be both: (i) at least 50 years of age, (ii) at high risk.</p> <p>For the purpose of administering this restriction, high risk is defined as the presence of at least two of the following conditions:</p> <ol style="list-style-type: none"> 1. The patient is in residential aged care, 2. The patient has disability with multiple comorbidities and/or frailty, 3. Neurological conditions, including stroke and dementia and demyelinating conditions, 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease, 5. Heart failure, coronary artery disease, cardiomyopathies, 6. Obesity (BMI greater than 30 kg/m²), 7. Diabetes type I or II, requiring medication for glycaemic control, 8. Renal impairment (eGFR less than 60mL/min), 9. Cirrhosis, or 10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness 	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13156</p>

			<p>classified by the Modified Monash Model as Category 5 or above. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records. For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p>	
	C13201		<p>SARS-CoV-2 infection Patient must have received a positive polymerase chain reaction (PCR) test result; OR Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND The treatment must be initiated within 5 days of symptom onset; OR The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic. Patient must be at least 70 years of age. Access to this drug through this restriction is permitted irrespective of vaccination status. Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13201</p>
	C13224		<p>SARS-CoV-2 infection Patient must have received a positive polymerase chain reaction (PCR) test result; OR Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND The treatment must be initiated within 5 days of symptom onset. Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk. For the purpose of administering this restriction, high risk is defined as the presence of at least two of the following conditions: 1. The patient is in residential aged care, 2. The patient has disability with multiple comorbidities and/or frailty, 3. Neurological conditions, including stroke and dementia and demyelinating conditions, 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease, 5. Heart failure, coronary artery disease, cardiomyopathies, 6. Obesity (BMI greater than 30 kg/m²), 7. Diabetes type I or II, requiring medication for glycaemic control, 8. Renal impairment (eGFR less than 60mL/min), 9. Cirrhosis, or 10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records. For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 13224</p>

				<p>degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.</p> <p>Access to this drug through this restriction is permitted irrespective of vaccination status.</p> <p>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</p> <p>Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p> <p>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p>	
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[98] Schedule 4, Part 1, after entry for Nintedanib

insert:

Niraparib	C13202	P13202		<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer</p> <p>Initial treatment - first line treatment of a patient requiring a daily dose of up to 2 capsules</p> <p>The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND</p> <p>Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have previously received PBS-subsidised treatment with this drug for this condition.</p> <p>Patient must be undergoing treatment with this drug class for the first time; OR</p> <p>Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal.</p> <p>A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines.</p> <p>Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.</p>	Compliance with Authority Required procedures
	C13204	P13204		<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer</p> <p>Continuing treatment - first line treatment of a patient requiring a daily dose of 3 capsules</p> <p>Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p> <p>The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.</p>	Compliance with Authority Required procedures
	C13264	P13264		<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer</p> <p>Continuing treatment - first line treatment of a patient requiring a daily dose of up to 2 capsules</p> <p>Patient must have received previous PBS-subsidised treatment with this drug as first line maintenance therapy for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p> <p>The treatment must not exceed a total of 36 months of combined non-PBS-subsidised/PBS-subsidised treatment for patients who are in complete response.</p>	Compliance with Authority Required procedures
	C13273	P13273		<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer</p> <p>Initial treatment - first line treatment of a patient requiring a daily dose of 3 capsules</p> <p>The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND</p> <p>Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p>	Compliance with Authority Required procedures

			<p>Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Patient must be undergoing treatment with this drug class for the first time; OR Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal. A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines. Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.</p>	
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[99] Schedule 4, Part 1, entry for Nirmatrelvir and ritonavir

substitute:

Nirmatrelvir and ritonavir	C13155		<p>SARS-CoV-2 infection Patient must have received a positive polymerase chain reaction (PCR) test result; OR Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND Patient must be moderately to severely immunocompromised; AND Patient must be at risk of progression to severe disease due to immunocompromised status; AND The treatment must be initiated within 5 days of symptom onset. Patient must be at least 18 years of age. For the purpose of administering this restriction, 'moderately to severely immunocompromised' patients are those with: 1. Any primary or acquired immunodeficiency including: a. Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes, multiple myeloma and other plasma cell disorders, b. Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months), c. Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency; OR 2. Any significantly immunocompromising condition(s) where, in the last 3 months the patient has received: a. Chemotherapy or whole body radiotherapy, b. High-dose corticosteroids (at least 20 mg of prednisone per day, or equivalent) for at least 14 days in a month, or pulse corticosteroid therapy, c. Biological agents and other treatments that deplete or inhibit B cell or T cell function (abatacept, anti-CD20 antibodies, BTK inhibitors, JAK inhibitors, sphingosine 1-phosphate receptor modulators, anti-CD52 antibodies, anti-complement antibodies, anti-thymocyte globulin), d. Selected conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) including mycophenolate, methotrexate, leflunomide, azathioprine, 6-mercaptopurine (at least 1.5mg/kg/day), alkylating agents (e.g. cyclophosphamide, chlorambucil), and systemic calcineurin inhibitors (e.g. cyclosporin, tacrolimus); OR 3. Any significantly immunocompromising condition(s) where, in the last 12 months the patient has received rituximab; OR 4. Others with very high-risk conditions including Down Syndrome, cerebral palsy, congenital heart disease, thalassemia, sickle cell disease and other haemoglobinopathies; OR 5. People with disability with multiple comorbidities and/or frailty. Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13155
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				This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.	
	C13156			<p>SARS-CoV-2 infection</p> <p>Patient must have received a positive polymerase chain reaction (PCR) test result; OR</p> <p>Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner;</p> <p>AND</p> <p>Patient must have at least one sign or symptom attributable to COVID-19; AND</p> <p>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND</p> <p>The treatment must be initiated within 5 days of symptom onset.</p> <p>Patient must be both: (i) at least 50 years of age, (ii) at high risk.</p> <p>For the purpose of administering this restriction, high risk is defined as the presence of at least two of the following conditions:</p> <ol style="list-style-type: none"> 1. The patient is in residential aged care, 2. The patient has disability with multiple comorbidities and/or frailty, 3. Neurological conditions, including stroke and dementia and demyelinating conditions, 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease, 5. Heart failure, coronary artery disease, cardiomyopathies, 6. Obesity (BMI greater than 30 kg/m²), 7. Diabetes type I or II, requiring medication for glycaemic control, 8. Renal impairment (eGFR less than 60mL/min), 9. Cirrhosis, or 10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above. <p>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records.</p> <p>For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell.</p> <p>Access to this drug through this restriction is permitted irrespective of vaccination status.</p> <p>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</p> <p>Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p> <p>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13156
	C13201			<p>SARS-CoV-2 infection</p> <p>Patient must have received a positive polymerase chain reaction (PCR) test result; OR</p> <p>Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner;</p> <p>AND</p> <p>Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND</p> <p>The treatment must be initiated within 5 days of symptom onset; OR</p> <p>The treatment must be initiated as soon as possible after a diagnosis is confirmed where asymptomatic.</p> <p>Patient must be at least 70 years of age.</p> <p>Access to this drug through this restriction is permitted irrespective of vaccination status.</p> <p>Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record.</p> <p>Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record.</p> <p>This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13201

	C13224		<p>SARS-CoV-2 infection Patient must have received a positive polymerase chain reaction (PCR) test result; OR Patient must have received a positive rapid antigen test (RAT) result verified by a medical practitioner or nurse practitioner; AND Patient must have at least one sign or symptom attributable to COVID-19; AND Patient must not require hospitalisation for COVID-19 infection at the time of prescribing; AND The treatment must be initiated within 5 days of symptom onset. Patient must be each of: (i) identify as Aboriginal or Torres Strait Islander, (ii) at least 30 years of age, (iii) at high risk. For the purpose of administering this restriction, high risk is defined as the presence of at least two of the following conditions:</p> <ol style="list-style-type: none"> 1. The patient is in residential aged care, 2. The patient has disability with multiple comorbidities and/or frailty, 3. Neurological conditions, including stroke and dementia and demyelinating conditions, 4. Respiratory compromise, including COPD, moderate or severe asthma (required inhaled steroids), and bronchiectasis, or caused by neurological or musculoskeletal disease, 5. Heart failure, coronary artery disease, cardiomyopathies, 6. Obesity (BMI greater than 30 kg/m²), 7. Diabetes type I or II, requiring medication for glycaemic control, 8. Renal impairment (eGFR less than 60mL/min), 9. Cirrhosis, or 10. The patient has reduced, or lack of, access to higher level healthcare and lives in an area of geographic remoteness classified by the Modified Monash Model as Category 5 or above. <p>Details of the patient's medical condition necessitating use of this drug must be recorded in the patient's medical records. For the purpose of administering this restriction, signs or symptoms attributable to COVID-19 are: fever greater than 38 degrees Celsius, chills, cough, sore throat, shortness of breath or difficulty breathing with exertion, fatigue, nasal congestion, runny nose, headache, muscle or body aches, nausea, vomiting, diarrhea, loss of taste, loss of smell. Access to this drug through this restriction is permitted irrespective of vaccination status. Where PCR is used to confirm diagnosis, the result, testing date, location and test provider must be recorded on the patient record. Where a RAT is used to confirm diagnosis, the test must be verified by a medical practitioner or nurse practitioner. The test result, testing date, location and test provider (where relevant) must be recorded on the patient record. This drug is not PBS-subsidised for pre-exposure or post-exposure prophylaxis for the prevention of SARS-CoV-2 infection.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 13224
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[100] Schedule 4, Part 1, entry for Olaparib

(a) *omit:*

	C10914	P10914	<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Initial treatment - first line treatment The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIg) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines. Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.</p>	Compliance with Authority Required procedures
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(b) *insert in numerical order after existing text:*

	C13226	P13226		<p>High grade stage III/IV epithelial ovarian, fallopian tube or primary peritoneal cancer Initial treatment - first line treatment The condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; AND Patient must be in partial or complete response to the immediately preceding platinum-based chemotherapy regimen prior to commencing treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have previously received PBS-subsidised treatment with this drug for this condition. Patient must be undergoing treatment with this drug class for the first time; OR Patient must be undergoing treatment with this drug class on a subsequent occasion, but only because there was an intolerance/contraindication to another drug in the same class that required permanent treatment withdrawal. A response (complete or partial) to the platinum-based chemotherapy regimen is to be assessed using either Gynaecologic Cancer InterGroup (GCIG) or Response Evaluation Criteria in Solid Tumours (RECIST) guidelines. Evidence of a BRCA1 or BRCA2 gene mutation must be derived through germline or somatic mutation testing.</p>	Compliance with Authority Required procedures
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[101] Schedule 4, Part 1, entry for Pembrolizumab

(a) *omit:*

	C9863			<p>Relapsed or Refractory Hodgkin lymphoma Initial treatment Patient must have undergone an autologous stem cell transplant (ASCT) for this condition and have experienced relapsed or refractory disease post ASCT; OR Patient must not be suitable for ASCT for this condition and have experienced relapsed or refractory disease following at least 2 prior treatments for this condition; AND Patient must not have received prior treatment with a PD-1 (programmed cell death-1) inhibitor for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a total of 7 doses under this restriction. Applications for authorisation of initial treatment must be in writing and must include: (a) a completed authority prescription form; (b) a completed Hodgkin lymphoma pembrolizumab PBS Authority Application.</p>	Compliance with Written Authority Required procedures
	C9864			<p>Relapsed or Refractory Hodgkin lymphoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed a total of 35 cycles in a lifetime.</p>	Compliance with Authority Required procedures

(b) *omit:*

	C10679			<p>Relapsed or refractory primary mediastinal B-cell lymphoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The treatment must not exceed a total of 35 cycles in a lifetime.</p>	Compliance with Authority Required procedures
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(c) *omit:*

	C10702			<p>Relapsed or refractory primary mediastinal B-cell lymphoma Initial treatment The condition must be diagnosed as primary mediastinal B-cell lymphoma through histological investigation combined with at</p>	Compliance with Written Authority Required procedures
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			<p>least one of: (i) positron emission tomography - computed tomography (PET-CT) scan, (ii) PET scan, (iii) CT scan, with the results retained in the patient's medical records; AND</p> <p>Patient must have been treated with rituximab-based chemotherapy for this condition; AND</p> <p>Patient must be experiencing relapsed/refractory disease; AND</p> <p>Patient must be autologous stem cell transplant (ASCT) ineligible following a single line of treatment; OR</p> <p>Patient must have undergone an autologous stem cell transplant (ASCT); OR</p> <p>Patient must have been treated with at least 2 chemotherapy treatment lines for this condition, one of which must include rituximab-based chemotherapy; AND</p> <p>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</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>The treatment must not exceed a total of 7 doses under this restriction.</p> <p>Applications for authorisation of initial treatment must be in writing and must include:</p> <p>(a) a completed authority prescription form;</p> <p>(b) a completed primary mediastinal B-cell lymphoma pembrolizumab PBS Authority Application, which includes:</p> <p>(i) confirmation that histology results with PET/CT scans support a diagnosis of primary mediastinal B-cell lymphoma and are retained on the patient's medical records;</p> <p>(ii) details of prior treatments for this condition.</p>	
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(d) *omit:*

	C11993		<p>Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer</p> <p>Transitioning from non-PBS to PBS subsidised treatment - Grandfather treatment</p> <p>Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 August 2021; AND</p> <p>Patient must not have received prior PBS funded treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for colorectal cancer; AND</p> <p>Patient must have been untreated for this indication (i.e untreated for each of: (i) unresectable disease, (ii) metastatic disease), prior to initiating treatment with this drug; AND</p> <p>Patient must have stable or responding disease; AND</p> <p>Patient must have a WHO performance status of 0 or 1; AND</p> <p>Patient must have deficient mismatch repair (dMMR) colorectal cancer, as determined by immunohistochemistry test; AND</p> <p>The treatment must not exceed a total of 35 cycles or up to 24 months of treatment in a lifetime for this condition.</p> <p>A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.</p>	Compliance with Authority Required procedures
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(e) *insert in numerical order after existing text:*

	C13126		<p>Relapsed or Refractory Hodgkin lymphoma</p> <p>Initial treatment</p> <p>Patient must have undergone an autologous stem cell transplant (ASCT) for this condition and have experienced relapsed or refractory disease post ASCT; OR</p> <p>Patient must not be suitable for ASCT for this condition and have experienced relapsed or refractory disease following at least 2 prior treatments for this condition; AND</p> <p>Patient must not have received prior treatment with a PD-1 (programmed cell death-1) inhibitor for this condition; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>The treatment must not exceed a total of 7 doses under this restriction.</p> <p>Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail.</p> <p>If the application is submitted through HPOS upload or mail, it must include:</p> <p>(a) a completed authority prescription form; and</p>	Compliance with Written Authority Required procedures
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			(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	
	C13213		<p>Relapsed or refractory primary mediastinal B-cell lymphoma Initial treatment</p> <p>The condition must be diagnosed as primary mediastinal B-cell lymphoma through histological investigation combined with at least one of: (i) positron emission tomography - computed tomography (PET-CT) scan, (ii) PET scan, (iii) CT scan; AND Patient must be experiencing relapsed/refractory disease; AND Patient must be autologous stem cell transplant (ASCT) ineligible following a single line of treatment; OR Patient must have undergone an autologous stem cell transplant (ASCT); OR Patient must have been treated with at least 2 chemotherapy treatment lines for this condition, one of which must include rituximab-based chemotherapy; 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 The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a total of 7 doses under this restriction. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment), or be in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number/code or provider number) of the histology results with PET/CT scans that support a diagnosis of primary mediastinal B-cell lymphoma; and (b) details of prior treatments for this condition. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Written Authority Required procedures
	C13214		<p>Relapsed or refractory primary mediastinal B-cell lymphoma Continuing treatment</p> <p>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; AND The treatment must not exceed a total of 35 cycles in a lifetime.</p>	Compliance with Authority Required procedures
	C13245		<p>Relapsed or Refractory Hodgkin lymphoma Continuing treatment</p> <p>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; AND The treatment must not exceed a total of 35 cycles in a lifetime.</p>	Compliance with Authority Required procedures

[102] Schedule 4, Part 1, entry for Ponatinib

(a) omit entry for circumstances code "C13022" and substitute:

	C13022	P13022	<p>Chronic Myeloid Leukaemia (CML) First continuing treatment</p> <p>Patient must have received initial PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have demonstrated a major cytogenetic response of less than 35% Philadelphia positive bone marrow cells in the preceding 18 months and thereafter at 12 monthly intervals; OR</p>	Compliance with Written Authority Required procedures
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			<p>Patient must demonstrated a peripheral blood level of BCR-ABL of less than 1% on the international scale in the preceding 18 months and thereafter at 12 monthly intervals.</p> <p>The first continuing application for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(i) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a major cytogenetic response [see Note explaining definitions of response]; or</p> <p>(ii) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating a peripheral blood level of BCR-ABL of less than 1% on the international scale [see Note explaining definitions of response].</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	
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(b) omit entry for circumstances code "C13025" and substitute:

	C13025	P13025	<p>Chronic Myeloid Leukaemia (CML)</p> <p>Initial treatment</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; OR</p> <p>Patient must have developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal; AND</p> <p>Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority; OR</p> <p>Patient must have developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal; OR</p> <p>Patient must not be eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis.</p> <p>Failure of an adequate trial of dasatinib or nilotinib is defined as:</p> <ol style="list-style-type: none"> 1. Lack of response to dasatinib or nilotinib therapy, defined as either: <ul style="list-style-type: none"> (i) failure to achieve a haematological response after a minimum of 3 months therapy with dasatinib or nilotinib; or (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or (iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with dasatinib or nilotinib; OR 2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing dasatinib or nilotinib therapy; OR 3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing dasatinib or nilotinib therapy; OR 4. Development of accelerated phase or blast crisis in a patient previously prescribed dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR 5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia. <p>Accelerated phase is defined by the presence of 1 or more of the following:</p> <ol style="list-style-type: none"> 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or 2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or 3. Peripheral basophils greater than or equal to 20%; or 4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 	Compliance with Written Authority Required procedures
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			<p>weeks; or</p> <p>5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome). Blast crisis is defined as either:</p> <ol style="list-style-type: none"> 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or 2. Extramedullary involvement other than spleen and liver. <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or</p> <p>(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and</p> <p>(iii) where there has been a loss of response to dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.</p> <p>All reports must be documented in the patient's medical records</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Up to a maximum of 18 months of treatment may be authorised under this initial restriction.</p>	
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(c) omit entry for circumstances code "C13030" and substitute:

	C13030	P13030	<p>Chronic Myeloid Leukaemia (CML) Initial treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must be expressing the T315I mutation confirmed through a bone marrow biopsy pathology report; AND Patient must have failed an adequate trial of imatinib confirmed through a pathology report from an Approved Pathology Authority; OR Patient must have failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority; OR Patient must have failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority. Failure of an adequate trial of imatinib or dasatinib or nilotinib is defined as:</p> <ol style="list-style-type: none"> 1. Lack of response to imatinib or dasatinib or nilotinib therapy, defined as either: <ol style="list-style-type: none"> (i) failure to achieve a haematological response after a minimum of 3 months therapy with imatinib or dasatinib or nilotinib; or (ii) failure to achieve any cytogenetic response after a minimum of 6 months therapy with imatinib or dasatinib or nilotinib as demonstrated on bone marrow biopsy by presence of greater than 95% Philadelphia chromosome positive cells; or (iii) failure to achieve a major cytogenetic response or a peripheral blood BCR-ABL level of less than 1% after a minimum of 12 months therapy with imatinib or dasatinib or nilotinib; OR 2. Loss of a previously documented major cytogenetic response (demonstrated by the presence of greater than 35% Ph positive cells on bone marrow biopsy), during ongoing imatinib or dasatinib or nilotinib therapy; OR 3. Loss of a previously demonstrated molecular response (demonstrated by peripheral blood BCR-ABL levels increasing consecutively in value by at least 5 fold to a level of greater than 0.1% confirmed on a subsequent test), during ongoing imatinib or dasatinib or nilotinib therapy; OR 4. Development of accelerated phase or blast crisis in a patient previously prescribed imatinib or dasatinib or nilotinib for any phase of chronic myeloid leukaemia; OR 5. Disease progression (defined as a greater than or equal to 50% increase in peripheral white blood cell count, blast count, basophils or platelets) during imatinib or dasatinib or nilotinib therapy in patients with accelerated phase or blast crisis chronic myeloid leukaemia. 	Compliance with Written Authority Required procedures
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			<p>Accelerated phase is defined by the presence of 1 or more of the following:</p> <ol style="list-style-type: none"> 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 15% but less than 30%; or 2. Percentage of blasts plus promyelocytes in the peripheral blood or bone marrow greater than or equal to 30%, provided that blast count is less than 30%; or 3. Peripheral basophils greater than or equal to 20%; or 4. Progressive splenomegaly to a size greater than or equal to 10 cm below the left costal margin to be confirmed on 2 occasions at least 4 weeks apart, or a greater than or equal to 50% increase in size below the left costal margin over 4 weeks; or 5. Karyotypic evolution (chromosomal abnormalities in addition to a single Philadelphia chromosome). <p>Blast crisis is defined as either:</p> <ol style="list-style-type: none"> 1. Percentage of blasts in the peripheral blood or bone marrow greater than or equal to 30%; or 2. Extramedullary involvement other than spleen and liver. <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(i) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating the patient has active chronic myeloid leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome; or</p> <p>(ii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy/peripheral blood pathology report demonstrating RT-PCR level of BCR-ABL transcript greater than 0.1% on the international scale; and</p> <p>(iii) details (date, unique identifying number/code or provider number) of a bone marrow biopsy pathology report demonstrating evidence of the T315I mutation; and</p> <p>(iv) where there has been a loss of response to imatinib or dasatinib or nilotinib, details (date, unique identifying number/code or provider number) of the confirming pathology report(s) from an Approved Pathology Authority or details of the dates of assessment in the case of progressive splenomegaly or extramedullary involvement.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Up to a maximum of 18 months of treatment may be authorised under this initial restriction.</p>	
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[103] Schedule 4, Part 1, entry for Rituximab

(a) *insert after entry for circumstances code "C7400":*

	C9446		<p>Severe active rheumatoid arthritis Subsequent continuing treatment Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have 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 given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9446
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				<p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response 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.</p> <p>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	
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(b) *insert after entry for circumstances code "C9542":*

	C9611			<p>Severe active rheumatoid arthritis</p> <p>Subsequent continuing treatment</p> <p>Must be treated by a rheumatologist; OR</p> <p>Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction; AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug; AND</p> <p>The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.</p> <p>Patient must be aged 18 years or older.</p> <p>An adequate response to treatment is defined as:</p> <p>an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;</p> <p>AND either of the following:</p> <p>(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</p> <p>(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:</p> <p>(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or</p> <p>(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response 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.</p> <p>The measurement of response to the prior course of therapy must be documented in the patient's medical notes.</p> <p>If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.</p> <p>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.</p>	Compliance with Authority Required procedures - Streamlined Authority Code 9611
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[104] Schedule 4, Part 1, entry for Rivaroxaban

omit:

	C4369	P4369		<p>Prevention of venous thromboembolism</p> <p>Patient must be undergoing total hip replacement.</p>	Compliance with Authority Required procedures -
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				Patient must require up to 20 days supply to complete a course of treatment.	Streamlined Authority Code 4369
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[105] Schedule 4, Part 1, entry for Ruxolitinib

substitute:

Ruxolitinib	C13127	P13127		High risk and intermediate-2 risk myelofibrosis Initial treatment The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) Details (date, unique identifying number/code or provider number) of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and (b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures
	C13128	P13128		High risk and intermediate-2 risk myelofibrosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
	C13130	P13130		Intermediate-1 risk myelofibrosis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition.	Compliance with Authority Required procedures
	C13173	P13173		Intermediate-1 risk myelofibrosis Initial treatment The condition must be either: (i) primary myelofibrosis, (ii) post-polycythemia vera myelofibrosis, (iii) post-essential thrombocythemia myelofibrosis, confirmed through a bone marrow biopsy report; AND Patient must have severe disease-related symptoms that are resistant, refractory or intolerant to available therapy. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: a) Details (date, unique identifying number/code or provider number) of the bone marrow biopsy report confirming diagnosis of myelofibrosis; and b) A classification of risk of myelofibrosis according to either the IPSS, DIPSS, or the Age-Adjusted DIPSS; and c) A confirmation that the patient's disease related symptoms are resistant, refractory or intolerant to available therapy. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).	Compliance with Written Authority Required procedures

[106] Schedule 4, Part 1, after entry for Selexipag

insert:

Selinexor	C13115	P13115	<p>Relapsed and/or refractory multiple myeloma Initial treatment - Dose requirement of 80 mg or 60 mg per week The treatment must be in combination with dexamethasone; AND Patient must have progressive disease after at least four prior lines of therapy for this condition; AND Patient must not have previously received this drug for this condition; AND Patient must have demonstrated refractory disease to the following prior treatments for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody; AND Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner. A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.</p>	Compliance with Authority Required procedures
	C13116	P13116	<p>Relapsed and/or refractory multiple myeloma Initial treatment - Dose requirement of 100 mg per week The treatment must be in combination with dexamethasone; AND Patient must have progressive disease after at least four prior lines of therapy for this condition; AND Patient must not have previously received this drug for this condition; AND Patient must have demonstrated refractory disease to the following prior treatments for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody; AND Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p>	Compliance with Authority Required procedures

			<p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy</p> <p>A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.</p> <p>A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.</p>	
	C13118	P13118	<p>Relapsed and/or refractory multiple myeloma</p> <p>Continuing treatment - Dose requirement of 100 mg per week</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be in combination with dexamethasone; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	Compliance with Authority Required procedures
	C13159	P13159	<p>Relapsed and/or refractory multiple myeloma</p> <p>Initial treatment - Dose requirement of 160 mg per week</p> <p>The treatment must be in combination with dexamethasone; AND</p> <p>Patient must have progressive disease after at least four prior lines of therapy for this condition; AND</p> <p>Patient must not have previously received this drug for this condition; AND</p> <p>Patient must have demonstrated refractory disease to the following prior treatments for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.</p> <p>Progressive disease is defined as at least 1 of the following:</p>	Compliance with Authority Required procedures

			<p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy</p> <p>A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.</p> <p>A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.</p>	
	C13160	P13160	<p>Relapsed and/or refractory multiple myeloma</p> <p>Continuing treatment - Dose requirement of 160 mg per week</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be in combination with dexamethasone; AND</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	Compliance with Authority Required procedures
	C13161	P13161	<p>Relapsed and/or refractory multiple myeloma</p> <p>Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 160 mg per week</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022; AND</p> <p>The treatment must be in combination with dexamethasone; AND</p> <p>Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy</p>	Compliance with Authority Required procedures

			<p>with this drug for this condition; AND</p> <p>Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	
	C13228	P13228	<p>Relapsed and/or refractory multiple myeloma</p> <p>Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 100 mg per week</p> <p>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022; AND</p> <p>The treatment must be in combination with dexamethasone; AND</p> <p>Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy with this drug for this condition; AND</p> <p>Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	Compliance with Authority Required procedures
	C13229	P13229	<p>Relapsed and/or refractory multiple myeloma</p> <p>Continuing treatment - Dose requirement of 80 mg or 60 mg per week</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p>	Compliance with Authority Required

			<p>The treatment must be in combination with dexamethasone; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	procedures
	C13256	P13256	<p>Relapsed and/or refractory multiple myeloma Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply - Dose requirement of 80 mg or 60 mg per week Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2022; AND The treatment must be in combination with dexamethasone; AND Patient must have progressive disease after at least four prior lines of therapy, prior to initiating non-PBS-subsidised therapy with this drug for this condition; AND Patient must have demonstrated refractory disease to prior treatments, prior to initiating non-PBS-subsidised therapy with this drug for this condition, which must include: (i) a minimum of two proteasome inhibitors; and (ii) a minimum of two immunomodulators; and (iii) an anti-CD38 monoclonal antibody; AND Patient must not be receiving concomitant PBS-subsidised treatment with any of the following: (i) proteasome inhibitors, (ii) Immunomodulators, (iii) anti-CD38 monoclonal antibody. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p>	Compliance with Authority Required procedures

[107] Schedule 4, Part 1, entry for Sonidegib

(a) omit entry for circumstances code "C7491" and substitute:

	C7491			<p>Metastatic or locally advanced basal cell carcinoma (BCC) Initial treatment or Continuing treatment – balance of supply Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
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(b) omit:

	C7540			<p>Metastatic or locally advanced basal cell carcinoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The condition must remain inappropriate for surgery; AND The condition must remain inappropriate for curative radiotherapy; AND Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction. The authority application must be made in writing and must include: a) A completed authority prescription form; and b) A completed Basal Cell Carcinoma Continuing PBS Authority Application Form - Supporting Information Form; and c) A confirmation statement from the treating doctor that the disease has not progressed; and d) In patients with locally advanced BCC, a letter from a surgically qualified clinician demonstrating that the condition remains inappropriate for surgery; or a letter from a radiation oncologist demonstrating that the condition remains inappropriate for curative radiotherapy The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria. Inappropriate for surgery is defined as: i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or iii/ Medical contraindication to surgery Inappropriate for curative radiotherapy is defined as: i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or ii/ Limitations due to location of tumour; or iii/ Limitations due to cumulative prior radiotherapy dose; or iv/ Progressive disease despite prior irradiation of locally advanced BCC</p>	Compliance with Written Authority Required procedures
	C7557			<p>Metastatic or locally advanced basal cell carcinoma Initial treatment The condition must be inappropriate for surgery; AND The condition must be inappropriate for curative radiotherapy; AND Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; OR Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal; AND Patient must not receive more than 16 weeks of treatment under this restriction. The authority application must be made in writing and must include:</p>	Compliance with Written Authority Required procedures

			<p>a) A completed authority prescription form; and b) A completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and c) A histological confirmation of BCC and whether the condition is metastatic or locally advanced; and d) A letter from a surgically qualified clinician demonstrating inappropriateness for surgery for patients with locally advanced BCC; and e) A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy for patients with locally advanced BCC; and f) A signed patient acknowledgement.</p> <p>The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.</p> <p>Inappropriate for surgery is defined as:</p> <p>i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or or ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or iii/ Medical contraindication to surgery</p> <p>Inappropriate for curative radiotherapy is defined as:</p> <p>i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or ii/ Limitations due to location of tumour; or iii/ Limitations due to cumulative prior radiotherapy dose; or iv/ Progressive disease despite prior irradiation of locally advanced BCC.</p>	
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(c) *insert in numerical order after existing text:*

	C13175		<p>Metastatic or locally advanced basal cell carcinoma (BCC) Initial treatment The condition must be inappropriate for surgery; AND The condition must be inappropriate for curative radiotherapy; AND Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; OR Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal; AND Patient must not receive more than 16 weeks of treatment under this restriction. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and (b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and (c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.</p> <p>The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.</p> <p>All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the</p>	Compliance with Written Authority Required procedures
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			<p>website specified in the Administrative Advice).</p> <p>Inappropriate for surgery is defined as:</p> <p>(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or</p> <p>(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or</p> <p>(iii) Medical contraindication to surgery.</p> <p>Inappropriate for curative radiotherapy is defined as:</p> <p>(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or</p> <p>(ii) Limitations due to location of tumour; or</p> <p>(iii) Limitations due to cumulative prior radiotherapy dose; or</p> <p>(iv) Progressive disease despite prior irradiation of locally advanced BCC.</p> <p>For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.</p>	
	C13260		<p>Metastatic or locally advanced basal cell carcinoma (BCC)</p> <p>Continuing treatment</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND</p> <p>The condition must remain inappropriate for surgery; AND</p> <p>The condition must remain inappropriate for curative radiotherapy; AND</p> <p>Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(a) Confirmation from the treating doctor that the disease has not progressed; and</p> <p>(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy.</p> <p>The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Inappropriate for surgery is defined as:</p> <p>(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or</p> <p>(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or</p> <p>(iii) Medical contraindication to surgery.</p> <p>Inappropriate for curative radiotherapy is defined as:</p> <p>(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or</p> <p>(ii) Limitations due to location of tumour; or</p> <p>(iii) Limitations due to cumulative prior radiotherapy dose; or</p> <p>(iv) Progressive disease despite prior irradiation of locally advanced BCC.</p> <p>For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating</p>	Compliance with Written Authority Required procedures

				inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.	
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[108] Schedule 4, Part 1, entry for Sunitinib

(a) *omit:*

	C7430	P7430		Metastatic or unresectable malignant gastrointestinal stromal tumour Continuing treatment Patient must have received an initial authority prescription for this drug for this condition; AND The treatment must be as monotherapy; AND Patient must have a WHO performance status of 2 or less; AND Patient must not have progressive disease.	Compliance with Authority Required procedures - Streamlined Authority Code 7430
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(b) *omit:*

	C12319	P12319		Metastatic or unresectable malignant gastrointestinal stromal tumour Initial treatment The treatment must be as monotherapy; AND Patient must have a WHO performance status of 2 or less; AND Patient must have previously failed or be intolerant to imatinib mesilate. Applications for authorisation must be in writing and must include: (1) a completed authority prescription form; and (2) a completed Sunitinib PBS Authority Application for Use in the Treatment of Gastrointestinal Stromal Tumour - Supporting Information Form; and (3) a signed patient acknowledgement. Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib	Compliance with Written Authority Required procedures
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(c) *insert in numerical order after existing text:*

	C13152	P13152		Metastatic or unresectable malignant gastrointestinal stromal tumour Initial treatment The condition must not be resectable; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have a WHO performance status of 2 or less; AND Patient must have previously failed or be intolerant to imatinib mesilate. Applications for authorisation must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) A completed authority prescription form; and (b) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). Patients who have failed to respond or are intolerant to imatinib are no longer eligible to receive PBS-subsidised imatinib.	Compliance with Written Authority Required procedures
	C13153	P13153		Metastatic or unresectable malignant gastrointestinal stromal tumour Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The condition must not be resectable; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND Patient must have a WHO performance status of 2 or less; AND	Compliance with Authority Required procedures - Streamlined Authority Code 13153

				Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.	
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[109] Schedule 4, Part 1, entry for Trastuzumab emtansine

omit entry for circumstance code "C13004" and substitute:

	C13004			<p>Early HER2 positive breast cancer Initial adjuvant treatment The treatment must be prescribed within 12 weeks after surgery; AND Patient must have, prior to commencing treatment with this drug, evidence of residual invasive cancer in the breast and/or axillary lymph nodes following completion of surgery, as demonstrated by a pathology report; AND Patient must have completed systemic neoadjuvant therapy that included trastuzumab and taxane-based chemotherapy prior to surgery; AND The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure; AND The treatment must not extend beyond 42 weeks (14 cycles) duration under the initial and the continuing treatment restrictions combined. Authority applications for initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include: (a) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of surgery. The pathology report must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include: (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	Compliance with Written Authority Required procedures
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[110] Schedule 4, Part 1, entry for Upadacitinib

omit entry for circumstance code "C12499" and substitute:

	C12499	P12499		<p>Chronic severe atopic dermatitis Initial treatment with this drug of the whole body Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; AND The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands; AND Patient must not have experienced an inadequate response to this therapy. Must be treated by a dermatologist; OR Must be treated by a clinical immunologist; AND Patient must be undergoing treatment with this drug as the sole PBS-subsidised therapy with this PBS indication (combination with oral corticosteroids is permitted as these are not listed with the PBS indication: chronic severe atopic dermatitis).</p>	Compliance with Written Authority Required procedures
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			<p>Patient must be 12 years of age or older. State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application. Acceptable scores can be: (a) current scores; or (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records. Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.</p>	
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[111] Schedule 4, Part 1, entry for Vedolizumab

(a) omit:

	C12077	P12077	<p>Severe Crohn disease Initial PBS-subsidised treatment (Grandfather patient) - subcutaneous form 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 a documented history of severe Crohn disease; AND Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 September 2021; AND Patient must have previously received induction treatment consisting of at least 2 doses with this drug for this condition in the intravenous form; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND Patient must have had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with this drug; 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; 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; OR Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form; AND Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (a) a completed authority prescription form(s); and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). The authority application must include 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</p>	Compliance with Written Authority Required procedures
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			<p>(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</p> <p>(iii) the date of most recent clinical assessment.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.</p> <p>A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.</p>	
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(b) omit:

	C12218	P12218	<p>Severe Crohn disease</p> <p>Balance of supply for Initial treatment, Continuing treatment or Grandfather patient - subcutaneous form</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); OR</p> <p>Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Grandfather treatment to complete 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR</p> <p>The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form; OR</p> <p>The treatment must provide no more than the balance of up to 24 weeks therapy under Initial PBS-subsidised treatment (Grandfather patient) - subcutaneous form.</p> <p>Patient must be aged 18 years or older.</p>	Compliance with Authority Required procedures
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(c) omit:

	C12244	P12244	<p>Moderate to severe ulcerative colitis</p> <p>Initial PBS-subsidised treatment (Grandfather patient) - subcutaneous form</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 September 2021; AND</p> <p>Patient must have previously received induction treatment consisting of at least 2 doses with this drug for this condition in the intravenous form; AND</p> <p>Patient must have had a Mayo clinic score greater than or equal to 6 prior to commencing non-PBS-subsidised treatment</p>	Compliance with Written Authority Required procedures
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			<p>with this drug for this condition; OR</p> <p>Patient must have had a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores were both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo score) prior to commencing non-PBS-subsidised treatment with this drug for this condition; OR</p> <p>Patient must have a documented history of moderate to severe refractory ulcerative colitis prior to having commenced non-PBS-subsidised treatment with this drug for this condition where a Mayo clinic or partial Mayo clinic baseline assessment is not available; AND</p> <p>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; OR</p> <p>Patient must have demonstrated an adequate response to treatment with this drug in the intravenous form; AND</p> <p>Patient must be appropriately assessed for the risk of developing progressive multifocal leukoencephalopathy whilst on this treatment.</p> <p>Patient must be aged 18 years or older.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(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).</p> <p>The authority application form must include the following:</p> <p>(i) the completed baseline Mayo clinic or partial Mayo clinic calculation sheet prior to initiating treatment (if available) and current Mayo clinic or partial Mayo clinic calculation sheet to demonstrate response, including the date of assessment; and</p> <p>(ii) If the baseline Mayo or partial Mayo clinic calculation is not available, reason must be provided; and</p> <p>(iii) the date of commencement of this drug.</p> <p>The current Mayo clinic or partial Mayo clinic assessment must be no more than 4 weeks old at the time of application. The baseline assessment must be from immediately prior to commencing treatment with this drug.</p> <p>Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.</p> <p>A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.</p>	
	C12250	P12250	<p>Moderate to severe ulcerative colitis</p> <p>Balance of supply for Initial treatment, Continuing treatment or Grandfather patient - subcutaneous form</p> <p>Must be treated by a gastroenterologist (code 87); OR</p> <p>Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR</p> <p>Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].</p> <p>Patient must have received insufficient therapy with this drug under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); OR</p> <p>Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment; OR</p> <p>Patient must have received insufficient therapy with this drug under the Grandfather treatment to complete 24 weeks of treatment; AND</p> <p>The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR</p> <p>The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form; OR</p> <p>The treatment must provide no more than the balance of up to 24 weeks therapy under Initial PBS-subsidised treatment (Grandfather patient) - subcutaneous form.</p> <p>Patient must be aged 18 years or older.</p>	Compliance with Authority Required procedures

(d) *insert in numerical order after existing text:*

	C13236	P13236		<p>Severe Crohn disease Balance of supply - subcutaneous form 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 under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); OR Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.</p>	Compliance with Authority Required procedures
	C13237	P13237		<p>Moderate to severe ulcerative colitis Balance of supply - subcutaneous form 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 under the Initial treatment with subcutaneous form to complete 14 to 16 weeks Initial treatment (intravenous and subcutaneous inclusive); OR Patient must have received insufficient therapy with this drug under the Continuing treatment to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of doses up to 14 to 16 weeks therapy available under Initial treatment - subcutaneous form; OR The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment - subcutaneous form.</p>	Compliance with Authority Required procedures

[112] Schedule 4, Part 1, entry for Vismodegib

(a) omit entry for circumstances code "C7491" and substitute:

	C7491			<p>Metastatic or locally advanced basal cell carcinoma (BCC) Initial treatment or Continuing treatment – balance of supply Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete maximum of 16 weeks of treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete maximum of 16 weeks of treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.</p>	Compliance with Authority Required procedures
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(b) omit:

C7540			<p>Metastatic or locally advanced basal cell carcinoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND The condition must remain inappropriate for surgery; AND The condition must remain inappropriate for curative radiotherapy; AND Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction. The authority application must be made in writing and must include: a) A completed authority prescription form; and b) A completed Basal Cell Carcinoma Continuing PBS Authority Application Form - Supporting Information Form; and c) A confirmation statement from the treating doctor that the disease has not progressed; and d) In patients with locally advanced BCC, a letter from a surgically qualified clinician demonstrating that the condition remains inappropriate for surgery; or a letter from a radiation oncologist demonstrating that the condition remains inappropriate for curative radiotherapy The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria. Inappropriate for surgery is defined as: i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or iii/ Medical contraindication to surgery Inappropriate for curative radiotherapy is defined as: i/ Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or ii/ Limitations due to location of tumour; or iii/ Limitations due to cumulative prior radiotherapy dose; or iv/ Progressive disease despite prior irradiation of locally advanced BCC</p>	Compliance with Written Authority Required procedures
C7557			<p>Metastatic or locally advanced basal cell carcinoma Initial treatment The condition must be inappropriate for surgery; AND The condition must be inappropriate for curative radiotherapy; AND Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition; OR Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal; AND Patient must not receive more than 16 weeks of treatment under this restriction. The authority application must be made in writing and must include: a) A completed authority prescription form; and b) A completed Basal Cell Carcinoma Initial PBS Authority Application Form - Supporting Information Form; and c) A histological confirmation of BCC and whether the condition is metastatic or locally advanced; and d) A letter from a surgically qualified clinician demonstrating inappropriateness for surgery for patients with locally advanced BCC; and e) A letter from a radiation oncologist demonstrating inappropriateness for curative radiotherapy for patients with locally advanced BCC; and f) A signed patient acknowledgement. The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to</p>	Compliance with Written Authority Required procedures

			<p>completion of the course of treatment. It is recommended that an application is submitted to the Department of Human Services no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.</p> <p>Inappropriate for surgery is defined as:</p> <p>i/ Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or</p> <p>ii/ Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or</p> <p>iii/ Medical contraindication to surgery</p> <p>Inappropriate for curative radiotherapy is defined as:</p> <p>i/Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or</p> <p>ii/ Limitations due to location of tumour; or</p> <p>iii/ Limitations due to cumulative prior radiotherapy dose; or</p> <p>iv/ Progressive disease despite prior irradiation of locally advanced BCC.</p>	
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(c) *insert in numerical order after existing text:*

	C13175		<p>Metastatic or locally advanced basal cell carcinoma (BCC)</p> <p>Initial treatment</p> <p>The condition must be inappropriate for surgery; AND</p> <p>The condition must be inappropriate for curative radiotherapy; AND</p> <p>Patient must not have received previous PBS-subsidised treatment with another hedgehog (Hh) inhibitor for this condition;</p> <p>OR</p> <p>Patient must have developed intolerance to another hedgehog (Hh) inhibitor of a severity necessitating permanent treatment withdrawal; AND</p> <p>Patient must not receive more than 16 weeks of treatment under this restriction.</p> <p>The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <p>(a) Details (date, unique identifying number/code or provider number) of the histological confirmation of BCC and whether the condition is metastatic or locally advanced; and</p> <p>(b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that surgery is inappropriate; and</p> <p>(c) In patients with locally advanced BCC, written confirmation from a radiation oncologist that curative radiotherapy is inappropriate.</p> <p>The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria.</p> <p>All reports must be documented in the patient's medical records.</p> <p>If the application is submitted through HPOS form upload or mail, it must include:</p> <p>(i) A completed authority prescription form; and</p> <p>(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p> <p>Inappropriate for surgery is defined as:</p> <p>(i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or</p> <p>or</p> <p>(ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or</p> <p>(iii) Medical contraindication to surgery.</p> <p>Inappropriate for curative radiotherapy is defined as:</p> <p>(i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or</p>	Compliance with Written Authority Required procedures
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			<ul style="list-style-type: none"> (ii) Limitations due to location of tumour; or (iii) Limitations due to cumulative prior radiotherapy dose; or (iv) Progressive disease despite prior irradiation of locally advanced BCC. <p>For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery and written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.</p>	
	C13268		<p>Metastatic or locally advanced basal cell carcinoma (BCC) 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; AND The condition must remain inappropriate for surgery; AND The condition must remain inappropriate for curative radiotherapy; AND Patient must not receive more than 16 weeks of treatment per continuing treatment under this restriction. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:</p> <ul style="list-style-type: none"> (a) Confirmation from the treating doctor that the disease has not progressed; and (b) In patients with locally advanced BCC, written confirmation from a surgically qualified clinician that the condition remains inappropriate for surgery; or written confirmation from a radiation oncologist that the condition remains inappropriate for curative radiotherapy. <p>The assessment of the patient's response to this PBS-subsidised course of therapy must be made within the 4 weeks prior to completion of the course of treatment. If the application is made in writing, it is recommended that the application is submitted no less than 2 weeks prior to the date the next dose is due in order to ensure continuity of treatment for those patients who meet the continuation criteria. All reports must be documented in the patient's medical records. If the application is submitted through HPOS form upload or mail, it must include:</p> <ul style="list-style-type: none"> (i) A completed authority prescription form; and (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). <p>Inappropriate for surgery is defined as:</p> <ul style="list-style-type: none"> (i) Curative resection is unlikely, such as where BCC has recurred in the same location after two or more surgical procedures; or (ii) Anticipated substantial morbidity or deformity from surgery or requiring complicated reconstructive surgery (e.g. removal of all or part of a facial structure, such as nose, ear, eyelid, eye; or requirement for limb amputation or free tissue transfer); or (iii) Medical contraindication to surgery. <p>Inappropriate for curative radiotherapy is defined as:</p> <ul style="list-style-type: none"> (i) Hypersensitivity to radiation due to genetic syndrome such as Gorlin Syndrome; or (ii) Limitations due to location of tumour; or (iii) Limitations due to cumulative prior radiotherapy dose; or (iv) Progressive disease despite prior irradiation of locally advanced BCC. <p>For patients with locally advanced BCC, written confirmation from a surgically qualified clinician demonstrating inappropriateness for surgery or written confirmation from a radiation oncologist demonstrating inappropriateness for curative radiotherapy should be kept in the patient's medical records.</p>	Compliance with Written Authority Required procedures

[113] Schedule 4, Part 1, entry for Vorinostat

substitute:

Vorinostat	C13177	P13177		Cutaneous T-cell lymphoma Initial treatment	Compliance with Authority Required
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			<p>Patient must have received systemic treatment with chemotherapy; AND Patient must demonstrate relapsed or chemotherapy-refractory disease; AND Patient must be ineligible for stem cell transplant; AND The treatment must be the sole PBS-subsidised therapy for this condition. Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. If the application is submitted through HPOS form upload or mail, it must include: (a) a completed authority prescription form; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>	procedures
	C13246	P13246	<p>Cutaneous T-cell lymphoma 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; AND The treatment must be the sole PBS-subsidised therapy for this condition.</p>	Compliance with Authority Required procedures

[114] Schedule 5, after entry for Ondansetron in the form Wafer 8 mg [GRP-17042]

insert:

Oxybutynin	GRP-26553	Tablet containing oxybutynin hydrochloride 5 mg	Oral	Ditropan
		Tablet containing oxybutynin chloride 5 mg (s19A)	Oral	Oxybutynin Chloride (Novitium)