PB 42 of 2020

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2020 (No. 5)

National Health Act 1953

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

Dated 29th May 2020

THEA DANIEL
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health

1 Name of Instrument

(1) This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2020 (No. 5)*.

(2) This Instrument may also be cited as PB 42 of 2020.

2 Commencement

This Instrument commences on 1 June 2020.

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

Schedule 1 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012).

Schedule 1 Amendments

[1] Schedule 1, after entry for Amino acid formula with carbohydrate, vitamins, minerals and trace elements without phenylalanine

insert:

Amino acid formula with carbohydrate without phenylalanine	Tablets containing 0.92 g protein, 462 (PKU Easy Tablet)	Oral	PKU Easy Tablet	OH	MP NP	C4295	4	5	1

[2] Schedule 1, after entry for Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides in the form Oral powder 400 g (Neocate Junior)

insert:

Amino acid formula with fat, carbohydrate without methionine	Tablets containing 0.91 g protein, 462 (HCU Easy Tablet)	Oral	HCU Easy Tablet	OH	MP NP	C5534	5	5	1

[3] Schedule 1, after entry for Amino acid formula with fat, carbohydrate without phenylalanine

insert:

Amino acid formula with fat, carbohydrate without phenylalanine and tyrosine	Tablets containing 0.91 g protein, 462 (TYR Easy Tablet)	Oral	TYR Easy Tablet	OH	MP NP	C5533	4	5	1
Amino acid formula with fat, carbohydrate without valine, leucine and isoleucine	Tablets containing 0.91 g protein, 462 (MSUD Easy Tablet)	Oral	MSUD Easy Tablet	OH	MP NP	C5571	5	5	1

[4] Schedule 1, entry for Amitriptyline in each of the forms: Tablet containing amitriptyline hydrochloride 10 mg; Tablet containing amitriptyline hydrochloride 25 mg; and Tablet containing amitriptyline hydrochloride 50 mg

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

a	Amitriptyline Lupin	GQ	MP NP			50	2	50

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

(a) *omit from the column headed "Circumstances":* **C7963 C7984**

(b) *insert in numerical order in the column headed "Circumstances":* **C10426 C10454 C10455**

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

(a) *omit from the column headed "Circumstances":* **C7963**

(b) *omit from the column headed "Circumstances":* **C7984**

(c) *insert in numerical order in the column headed "Circumstances":* **C10426 C10454 C10455**

[7] **Schedule 1, entry for Budesonide with formoterol in the form Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses**

substitute:

Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	Inhalation by mouth	Symbicort Rapihaler 100/3	AP	MP NP	C4397 C10482	P10482	2	2	1
				MP NP	C4397 C10482	P4397	2	5	1

[8] **Schedule 1, entry for Budesonide with formoterol in the form Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses**

substitute:

Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses	Inhalation by mouth	a	DuoResp Spiromax	TB	MP NP	C7970 C10464	P10464	1	2	1
		a	Symbicort Turbuhaler 200/6	AP	MP NP	C7970 C10464	P10464	1	2	1
		a	DuoResp Spiromax	TB	MP NP	C7970 C10464	P7970	1	5	1
		a	Symbicort Turbuhaler 200/6	AP	MP NP	C7970 C10464	P7970	1	5	1

[9] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 5 mg *[Maximum Quantity: 2; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances" (all instances):* **C4951**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10445**

(c) *omit from the column headed "Purposes" (all instances):* **P4951** *substitute:* **P10445**

[10] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 5 mg *[Maximum Quantity: 4; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances" (all instances):* **C4951**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10445**

[11] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 10 mg *[Maximum Quantity: 2; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances" (all instances):* **C4951**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10445**

(c) *omit from the column headed "Purposes" (all instances):* **P4951** *substitute:* **P10445**

[12] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 10 mg *[Maximum Quantity: 4; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances" (all instances):* **C4951**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10445**

[13] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 15 mg *[Maximum Quantity: 2; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances" (all instances):* **C4951**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10445**

(c) *omit from the column headed "Purposes" (all instances):* **P4951** *substitute:* **P10445**

[14] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 15 mg *[Maximum Quantity: 4; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances" (all instances):* **C4951**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10445**

[15] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 20 mg *[Maximum Quantity: 2; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances" (all instances):* **C4951**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10445**

(c) *omit from the column headed "Purposes" (all instances):* **P4951** *substitute:* **P10445**

[16] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 20 mg *[Maximum Quantity: 4; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances" (all instances):* **C4951**

(b) *insert in numerical order in the column headed "Circumstances" (all instances):* **C10445**

[17] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 25 mg *[Maximum Quantity: 2; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C4951**

(b) *insert in numerical order in the column headed "Circumstances":* **C10445**

(c) *omit from the column headed "Purposes":* **P4951** *substitute:* **P10445**

[18] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 25 mg *[Maximum Quantity: 4; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C4951**

(b) *insert in numerical order in the column headed "Circumstances":* **C10445**

[19] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 30 mg *[Maximum Quantity: 2; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C4951**

(b) *insert in numerical order in the column headed "Circumstances":* **C10445**

(c) *omit from the column headed "Purposes":* **P4951** *substitute:* **P10445**

[20] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 30 mg *[Maximum Quantity: 4; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C4951**

(b) *insert in numerical order in the column headed "Circumstances":* **C10445**

[21] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 40 mg *[Maximum Quantity: 2; Number of Repeats: 0]***

(a) *omit from the column headed "Circumstances":* **C4951**

(b) *insert in numerical order in the column headed "Circumstances":* **C10445**

(c) *omit from the column headed "Purposes":* **P4951** *substitute:* **P10445**

[22] **Schedule 1, entry for Buprenorphine in the form Transdermal patch 40 mg *[Maximum Quantity: 4; Number of Repeats: 2]***

(a) *omit from the column headed "Circumstances":* **C4951**

(b) *insert in numerical order in the column headed "Circumstances":* **C10445**

[23] **Schedule 1, entry for Certolizumab pegol**

substitute:

Certolizumab pegol	Injection 200 mg in 1 mL single use pre-filled syringe	Injection	Cimzia	UC	MP	C8626 C8627 C8679 C8705 C8706 C8753 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10456 C10458 C10459 C10468 C10480 C10489	P10458 P10459 P10489	2	0	2
					MP	C8626 C8627 C8679 C8705 C8706 C8753 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10456 C10458 C10459 C10468 C10480 C10489	P8706 P9185 P9625	2	2	2
					MP	C8626 C8627 C8679 C8705 C8706 C8753 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431	P8627 P8679 P9063 P9105 P9430 P9431 P10431	2	5	2

					C9442 C9537 C9610 C9625 C10431 C10456 C10458 C10459 C10468 C10480 C10489				
				MP	C8626 C8627 C8679 C8705 C8706 C8753 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10456 C10458 C10459 C10468 C10480 C10489	P8626 P8705 P8753 P9073 P9074 P9183 P9442 P9537 P9610 P10456 P10468 P10480	6	0	2
Solution for injection 200 mg in 1 mL pre-filled pen	Injection	Cimzia	UC	MP	C8626 C8627 C8679 C8705 C8706 C8753 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10456 C10458 C10459 C10468 C10480 C10489	P10458 P10459 P10489	2	0	2
				MP	C8626 C8627 C8679 C8705 C8706 C8753 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10456 C10458 C10459 C10468 C10480 C10489	P8706 P9185 P9625	2	2	2
				MP	C8626 C8627 C8679 C8705	P8627 P8679 P9063 P9105	2	5	2

						C8706 C8753 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10456 C10458 C10459 C10468 C10480 C10489	P9430 P9431 P10431			
					MP	C8626 C8627 C8679 C8705 C8706 C8753 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10456 C10458 C10459 C10468 C10480 C10489	P8626 P8705 P8753 P9073 P9074 P9183 P9442 P9537 P9610 P10456 P10468 P10480	6	0	2

[24] Schedule 1, entry for Ciprofloxacin in the form Tablet 500 mg (as hydrochloride)

omit:

			a	Ciprofloxacin-BW	GQ	MP NP	C5614 C5615 C5687 C5688 C5689 C5722 C5780		14	0	14

[25] Schedule 1, entry for Codeine

substitute:

Codeine	Tablet containing codeine phosphate hemihydrate 30 mg	Oral		Aspen Pharma Pty Ltd	AS	MP NP	C10442 C10444 C10479	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
						MP NP	C10442 C10444 C10479	P10444 P10479	20	0	20
						PDP	C10442 C10446	P10446	20	0	20

[26] Schedule 1, entry for Codeine with paracetamol

substitute:

Codeine with paracetamol	Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg	Oral	a	APO-Paracetamol/Codeine 500/30	TX	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Codalgin Forte	AF	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Codapane Forte 500/30	AL	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Comfarol Forte	SZ	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Panadeine Forte	SW	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Paracetamol/Codeine GH 500/30	GQ	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Prodeine Forte	AV	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	APO-Paracetamol/ Codeine 500/30	TX	MP NP	C10442 C10444	P10444	20	0	20
						PDP	C10442 C10446	P10446	20	0	20
			a	Codalgin Forte	AF	MP NP	C10442 C10444	P10444	20	0	20
						PDP	C10442 C10446	P10446	20	0	20
			a	Codapane Forte 500/30	AL	MP NP	C10442 C10444	P10444	20	0	20
						PDP	C10442 C10446	P10446	20	0	20
			a	Comfarol Forte	SZ	MP NP	C10442 C10444	P10444	20	0	20
						PDP	C10442 C10446	P10446	20	0	20
			a	Panadeine Forte	SW	MP NP	C10442 C10444	P10444	20	0	20
						PDP	C10442 C10446	P10446	20	0	20

	a	Paracetamol/Codeine GH 500/30	GQ	MP NP	C10442 C10444	P10444	20	0	20
				PDP	C10442 C10446	P10446	20	0	20
	a	Prodeine Forte	AV	MP NP	C10442 C10444	P10444	20	0	20
				PDP	C10442 C10446	P10446	20	0	20

[27] Schedule 1, entry for Doxepin in each of the forms: Capsule 10 mg (as hydrochloride); and Capsule 25 mg (as hydrochloride)

omit:

		Sinequan	PF	MP NP			50	2	50

[28] Schedule 1, entry for Dutasteride with tamsulosin

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

	a	Doubluts	GC	MP NP	C6189		30	5	30

(b) *insert in the column headed "Schedule Equivalent" for the brand "Duodart 500ug/400ug":* **a**

[29] Schedule 1, entry for Fentanyl in the form Transdermal patch 1.28 mg

omit from the column headed "Circumstances": **C4952** *substitute:* **C10441**

[30] Schedule 1, entry for Fentanyl in each of the forms: Transdermal patch 2.063 mg; and Transdermal patch 2.1 mg

omit from the column headed "Circumstances" (all instances): **C4952** *substitute:* **C10441**

[31] Schedule 1, entry for Fentanyl in the form Transdermal patch 2.55 mg

omit from the column headed "Circumstances": **C4952** *substitute:* **C10441**

[32] Schedule 1, entry for Fentanyl in each of the forms: Transdermal patch 4.125 mg; and Transdermal patch 4.2 mg

omit from the column headed "Circumstances" (all instances): **C4952** *substitute:* **C10441**

[33] Schedule 1, entry for Fentanyl in each of the forms: Transdermal patch 5.10 mg; and Trandermal patch 7.65 mg

omit from the column headed "Circumstances": **C4952** *substitute:* **C10441**

[34] Schedule 1, entry for Fentanyl in each of the forms: Transdermal patch 8.25 mg; and Transdermal patch 8.4 mg

omit from the column headed "Circumstances" (all instances): **C4952** *substitute:* **C10441**

[35] Schedule 1, entry for Fentanyl in the form Transdermal patch 10.20 mg

omit from the column headed "Circumstances": **C4952** *substitute:* **C10441**

[36] Schedule 1, entry for Fentanyl in each of the forms: Transdermal patch 12.375 mg; Transdermal patch 12.6 mg; Transdermal patch 16.5 mg; and Transdermal patch 16.8 mg

omit from the column headed "Circumstances" (all instances): **C4952** *substitute:* **C10441**

[37] **Schedule 1, entry for Ferric derisomaltose**

substitute:

Ferric derisomaltose	Injection 500 mg (iron) in 5 mL	Injection	Monofer	PF	MP NP		3	0	1
	Injection 1000 mg (iron) in 10 mL	Injection	Monofer	PF	MP NP		1	1	1

[38] **Schedule 1, entry for Fluoxetine in the form Capsule 20 mg (as hydrochloride)**

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

a	BTC Fluoxetine	JB	MP NP	C4755 C6277	28	5	28	

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

a	Fluoxetine APOTEX	TY	MP NP	C4755 C6277	28	5	28	

[39] **Schedule 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C8155 C8201 C8223 C8224 C8225 C8229**

(b) *insert in numerical order in the column headed "Circumstances":* **C10434 C10435 C10436 C10461 C10490 C10491**

(c) *omit from the column headed "Purposes":* **P8201 P8223 P8229**

(d) *insert in numerical order in the column headed "Purposes":* **P10435 P10436 P10490 P10491**

[40] **Schedule 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C8155 C8201 C8223 C8224 C8225 C8229**

(b) *insert in numerical order in the column headed "Circumstances":* **C10434 C10435 C10436 C10461 C10490 C10491**

(c) *omit from the column headed "Purposes":* **P8155 P8224 P8225**

(d) *insert in numerical order in the column headed "Purposes":* **P10434 P10461**

[41] **Schedule 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 3]***

(a) *omit from the column headed "Circumstances":* **C8155 C8201 C8223 C8224 C8225 C8229**

(b) *insert in numerical order in the column headed "Circumstances":* **C10434 C10435 C10436 C10461 C10490 C10491**

(c) *omit from the column headed "Purposes":* **P8201 P8223 P8229**

(d) *insert in numerical order in the column headed "Purposes":* **P10435 P10436 P10490 P10491**

[42] **Schedule 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 5]***

(a) *omit from the column headed "Circumstances":* **C8155 C8201 C8223 C8224 C8225 C8229**

(b) *insert in numerical order in the column headed "Circumstances":* **C10434 C10435 C10436 C10461 C10490 C10491**

(c) *omit from the column headed "Purposes":* **P8155 P8224 P8225**

(d) *insert in numerical order in the column headed "Purposes":* **P10434 P10461**

[43] Schedule 1, entry for Hydromorphone

substitute:

Hydromorphone	Injection containing hydromorphone hydrochloride 2 mg in 1 mL	Injection	a	Dilaudid	MF	MP NP	C10439		5	0	5
			a	HYDROMORPHONE JUNO	JU	MP NP	C10439		5	0	5
			a	MEDSURGE HYDROMORPHONE 2 mg/1 mL	DZ	MP NP	C10439		5	0	5
	Injection containing hydromorphone hydrochloride 10 mg in 1 mL	Injection	a	Dilaudid-HP	MF	MP NP	C10439		5	0	5
			a	HYDROMORPHONE JUNO-HP	JU	MP NP	C10439		5	0	5
			a	MEDSURGE HYDROMORPHONE HP 10 mg/1 mL	DZ	MP NP	C10439		5	0	5
	Oral liquid containing hydromorphone hydrochloride 1 mg per mL, 200 mL	Oral		Dilaudid	MF	MP NP	C10439		1	0	1
						PDP	C10440		1	0	1
	Tablet containing hydromorphone hydrochloride 2 mg	Oral		Dilaudid	MF	MP NP	C10439 C10451	P10451	10	0	20
						PDP	C10440 C10451	P10451	10	0	20
						MP NP	C10439 C10451	P10439	20	0	20
						PDP	C10440 C10451	P10440	20	0	20
	Tablet (modified release) containing hydromorphone hydrochloride 4 mg	Oral		Jurnista	JC	MP NP	C10448		14	0	14
	Tablet containing hydromorphone hydrochloride 4 mg	Oral		Dilaudid	MF	MP NP	C10439 C10451	P10451	10	0	20
						PDP	C10440 C10451	P10451	10	0	20
						MP NP	C10439 C10451	P10439	20	0	20
						PDP	C10440 C10451	P10440	20	0	20
	Tablet (modified release) containing hydromorphone	Oral		Jurnista	JC	MP NP	C10448		14	0	14

	hydrochloride 8 mg											
	Tablet containing hydromorphone hydrochloride 8 mg	Oral	Dilaudid	MF	MP NP	C10439 C10451	P10451	10	0	20		
					PDP	C10440 C10451	P10451	10	0	20		
					MP NP	C10439 C10451	P10439	20	0	20		
					PDP	C10440 C10451	P10440	20	0	20		
	Tablet (modified release) containing hydromorphone hydrochloride 16 mg	Oral	Jurnista	JC	MP NP	C10448		14	0	14		
	Tablet (modified release) containing hydromorphone hydrochloride 32 mg	Oral	Jurnista	JC	MP NP	C10448		14	0	14		
	Tablet (modified release) containing hydromorphone hydrochloride 64 mg	Oral	Jurnista	JC	MP NP	C10448		14	0	14		

[44] Schedule 1, entry for Isotretinoin in each of the forms: Capsule 10 mg; and Capsule 20 mg

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

		a	Isotretinoin Lupin	GQ	MP	C5224		60	3	60	

[45] Schedule 1, entry for Lenalidomide in each of the forms: Capsule 5 mg; Capsule 10 mg; Capsule 15 mg; and Capsule 25 mg

insert as first entry:

					MP	See Note 3	See Note 3	See Note 3	See Note 3	14	D(100)

[46] Schedule 1, entry for Levodopa with carbidopa

omit:

	Tablet (modified release) 200 mg-50 mg	Oral	Carbidopa and Levodopa Extended-release Tablets	DZ	MP NP	C5253		100	5	100	

[47] Schedule 1, entry for Mepolizumab

insert as first entry:

	Injection 100 mg in 1 mL single dose pre-filled pen	Injection	Nucala	GK	MP	See Note 3	See Note 3	See Note 3	See Note 3	1	D(100)

[48] Schedule 1, entry for Metformin in the form Tablet containing metformin hydrochloride 1 g

omit:

	a	Metformin generichealth 1000	GQ	MP NP		90	5	90

[49] Schedule 1, entry for Methadone in the form Injection containing methadone hydrochloride 10 mg in 1 mL

omit from the column headed "Circumstances": **C4953** *substitute:* **C10441**

[50] Schedule 1, entry for Methadone in the form Tablet containing methadone hydrochloride 10 mg

omit from the column headed "Circumstances": **C4953** *substitute:* **C10441**

[51] Schedule 1, entry for Montelukast in the form Tablet, chewable, 4 mg (as sodium)

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

	a	Montelukast Lupin	HQ	MP NP	C6666	28	5	28

[52] Schedule 1, entry for Montelukast in the form Tablet, chewable, 5 mg (as sodium)

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

	a	Montelukast Lupin	HQ	MP NP	C6674 C7781	28	5	28

[53] Schedule 1, entry for Morphine

substitute:

Morphine	Capsule containing morphine sulfate pentahydrate 10 mg (containing sustained release pellets)	Oral	Kapanol	YN	MP NP	C9248 C10445	28	0	28
	Capsule containing morphine sulfate pentahydrate 20 mg (containing sustained release pellets)	Oral	Kapanol	YN	MP NP	C9248 C10445	28	0	28
	Capsule containing morphine sulfate pentahydrate 30 mg (controlled release)	Oral	MS Mono	MF	MP NP	C10445	14	0	14
	Capsule containing morphine sulfate pentahydrate 50 mg (containing sustained release pellets)	Oral	Kapanol	YN	MP NP	C10445	28	0	28
	Capsule containing morphine sulfate pentahydrate 60 mg	Oral	MS Mono	MF	MP NP	C10445	14	0	14

(controlled release)									
Capsule containing morphine sulfate pentahydrate 90 mg (controlled release)	Oral		MS Mono	MF	MP NP	C10445	14	0	14
Capsule containing morphine sulfate pentahydrate 100 mg (containing sustained release pellets)	Oral		Kapanol	YN	MP NP	C10445	28	0	28
Capsule containing morphine sulfate pentahydrate 120 mg (controlled release)	Oral		MS Mono	MF	MP NP	C10445	14	0	14
Injection containing morphine hydrochloride trihydrate 10 mg in 1 mL	Injection		Morphine Juno	JU	MP NP MW	C10472	5	0	5
					PDP	C10478	5	0	5
Injection containing morphine sulfate pentahydrate 10 mg in 1 mL	Injection		Hospira Pty Limited	PF	MP NP MW	C10472	5	0	5
					PDP	C10478	5	0	5
			MORPHINE SULFATE 10 mg/1 mL MEDSURGE	DZ	MP NP MW	C10472	5	0	5
					PDP	C10478	5	0	5
Injection containing morphine sulfate pentahydrate 15 mg in 1 mL	Injection	a	Hospira Pty Limited	PF	MP NP MW	C10472	5	0	5
					PDP	C10478	5	0	5
		a	MORPHINE SULFATE 15 mg/1 mL MEDSURGE	DZ	MP NP MW	C10472	5	0	5
					PDP	C10478	5	0	5
Injection containing morphine hydrochloride trihydrate 20 mg in 1 mL	Injection		Morphine Juno	JU	MP NP	C10472	5	0	5
					PDP	C10478	5	0	5
Injection containing morphine sulfate pentahydrate 30 mg in 1 mL	Injection	a	Hospira Pty Limited	PF	MP NP	C10472	5	0	5
					PDP	C10478	5	0	5
		a	MORPHINE SULFATE 30 mg/1 mL MEDSURGE	DZ	MP NP	C10472	5	0	5
					PDP	C10478	5	0	5
Injection containing morphine	Injection		Morphine Juno	JU	MP NP	C10472	5	0	5

hydrochloride trihydrate 50 mg in 5 mL								
Injection containing morphine hydrochloride trihydrate 100 mg in 5 mL	Injection	Morphine Juno	JU	MP NP	C10472	5	0	5
Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 200 mL	Oral	Ordine 2	MF	MP NP	C10439	1	0	1
				PDP	C10440	1	0	1
Oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 200 mL	Oral	Ordine 5	MF	MP NP	C10439	1	0	1
				PDP	C10440	1	0	1
Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 200 mL	Oral	Ordine 10	MF	MP NP	C10439	1	0	1
				PDP	C10440	1	0	1
Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 20 mg per sachet	Oral	MS Contin Suspension 20 mg	MF	MP NP	C10445	28	0	28
Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 30 mg per sachet	Oral	MS Contin Suspension 30 mg	MF	MP NP	C10445	28	0	28
Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 60 mg per sachet	Oral	MS Contin Suspension 60 mg	MF	MP NP	C10445	28	0	28
Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 100 mg per sachet	Oral	MS Contin Suspension 100 mg	MF	MP NP	C10445	28	0	28
Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 200 mg per sachet	Oral	MS Contin Suspension 200 mg	MF	MP NP	C10466 C10487	28	0	28
Tablet containing morphine sulfate pentahydrate 5 mg	Oral	MS Contin	MF	MP NP	C10445	28	0	28

(controlled release)										
Tablet containing morphine sulfate pentahydrate 10 mg	Oral		Sevredol	MF	MP NP	C6168 C10486	P10486	20	0	20
					MP NP	C6168 C10486	P6168	20	2	20
Tablet containing morphine sulfate pentahydrate 10 mg (controlled release)	Oral	a	Momex SR 10	RW	MP NP	C10445		28	0	28
		a	Morphine MR AN	EA	MP NP	C10445		28	0	28
		a	MORPHINE MR APOTEX	TX	MP NP	C10445		28	0	28
		a	Morphine MR Mylan	AF	MP NP	C10445		28	0	28
		a	MS Contin	MF	MP NP	C10445		28	0	28
Tablet containing morphine sulfate pentahydrate 15 mg (controlled release)	Oral		MS Contin	MF	MP NP	C10445		28	0	28
Tablet containing morphine sulfate pentahydrate 20 mg	Oral		Sevredol	MF	MP NP	C6168 C10486	P10486	20	0	20
					MP NP	C6168 C10486	P6168	20	2	20
Tablet containing morphine sulfate pentahydrate 30 mg	Oral		Anamorph	RW	MP NP	C10439 C10451	P10451	10	0	20
					PDP	C10440 C10451	P10451	10	0	20
					MP NP	C10439 C10451	P10439	20	0	20
					PDP	C10440 C10451	P10440	20	0	20
Tablet containing morphine sulfate pentahydrate 30 mg (controlled release)	Oral	a	Momex SR 30	RW	MP NP	C10445		28	0	28
		a	Morphine MR AN	EA	MP NP	C10445		28	0	28
		a	MORPHINE MR APOTEX	TX	MP NP	C10445		28	0	28
		a	Morphine MR Mylan	AF	MP NP	C10445		28	0	28
		a	MS Contin	MF	MP NP	C10445		28	0	28
Tablet containing morphine sulfate pentahydrate 60 mg (controlled release)	Oral	a	Momex SR 60	RW	MP NP	C10445		28	0	28
		a	Morphine MR AN	EA	MP NP	C10445		28	0	28
		a	MORPHINE MR APOTEX	TX	MP NP	C10445		28	0	28

			a	Morphine MR Mylan	AF	MP NP	C10445		28	0	28
			a	MS Contin	MF	MP NP	C10445		28	0	28
	Tablet containing morphine sulfate pentahydrate 100 mg (controlled release)	Oral	a	Momex SR 100	RW	MP NP	C10445		28	0	28
			a	Morphine MR AN	EA	MP NP	C10445		28	0	28
			a	MORPHINE MR APOTEX	TX	MP NP	C10445		28	0	28
			a	Morphine MR Mylan	AF	MP NP	C10445		28	0	28
			a	MS Contin	MF	MP NP	C10445		28	0	28
	Tablet containing morphine sulfate pentahydrate 200 mg (controlled release)	Oral		MS Contin	MF	MP NP	C6151 C10466 C10487	P10466 P10487	28	0	28
						MP NP	C6151 C10466 C10487	P6151	28	2	28

[54] Schedule 1, entry for Oxycodone

substitute:

Oxycodone	Capsule containing oxycodone hydrochloride 5 mg	Oral	a	Oxycodone BNM	LI	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	OxyNorm	MF	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Oxycodone BNM	LI	MP NP	C10442 C10444	P10444	20	0	20
						PDP	C10442 C10446	P10446	20	0	20
			a	OxyNorm	MF	MP NP	C10442 C10444	P10444	20	0	20
						PDP	C10442 C10446	P10446	20	0	20
	Capsule containing oxycodone hydrochloride 10 mg	Oral	a	Oxycodone BNM	LI	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	OxyNorm	MF	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Oxycodone BNM	LI	MP NP	C10442 C10444	P10444	20	0	20

					PDP	C10442 C10446	P10446	20	0	20
		a	OxyNorm	MF	MP NP	C10442 C10444	P10444	20	0	20
					PDP	C10442 C10446	P10446	20	0	20
Capsule containing oxycodone hydrochloride 20 mg	Oral	a	Oxycodone BNM	LI	MP NP	C10444		20	0	20
		a	OxyNorm	MF	MP NP	C10444		20	0	20
Oral solution containing oxycodone hydrochloride 1 mg per mL, 250 mL	Oral		OxyNorm Liquid 1mg/mL	MF	MP NP	C10444		1	0	1
					PDP	C10446		1	0	1
Suppository 30 mg (as pectinate)	Rectal		Proladone	FF	MP NP	C10477		12	0	12
					PDP	C10485		12	0	12
Tablet containing oxycodone hydrochloride 5 mg	Oral	a	Endone	AF	MP NP	C10442 C10444	P10442	10	0	20
					PDP	C10442 C10446	P10442	10	0	20
		a	Mayne Pharma Oxycodone IR	YN	MP NP	C10442 C10444	P10442	10	0	20
					PDP	C10442 C10446	P10442	10	0	20
		a	Oxycodone Aspen	AL	MP NP	C10442 C10444	P10442	10	0	20
					PDP	C10442 C10446	P10442	10	0	20
		a	Endone	AF	MP NP	C10442 C10444	P10444	20	0	20
					PDP	C10442 C10446	P10446	20	0	20
		a	Mayne Pharma Oxycodone IR	YN	MP NP	C10442 C10444	P10444	20	0	20
					PDP	C10442 C10446	P10446	20	0	20
		a	Oxycodone Aspen	AL	MP NP	C10442 C10444	P10444	20	0	20
					PDP	C10442 C10446	P10446	20	0	20
Tablet containing oxycodone hydrochloride 10 mg (controlled release)	Oral	a	Novacodone	HX	MP NP	C10445		28	0	28
		a	Oxycodone Sandoz	SZ	MP NP	C10445		28	0	28
		a	OxyContin	MF	MP NP	C10445		28	0	28
Tablet containing oxycodone hydrochloride 15 mg (controlled release)	Oral		OxyContin	MF	MP NP	C10445		28	0	28

Tablet containing oxycodone hydrochloride 20 mg (controlled release)	Oral	a	Novacodone	HX	MP NP	C10445	28	0	28
		a	Oxycodone Sandoz	SZ	MP NP	C10445	28	0	28
		a	OxyContin	MF	MP NP	C10445	28	0	28
Tablet containing oxycodone hydrochloride 30 mg (controlled release)	Oral		OxyContin	MF	MP NP	C10445	28	0	28
Tablet containing oxycodone hydrochloride 40 mg (controlled release)	Oral	a	Novacodone	HX	MP NP	C10445	28	0	28
		a	Oxycodone Sandoz	SZ	MP NP	C10445	28	0	28
		a	OxyContin	MF	MP NP	C10445	28	0	28
Tablet containing oxycodone hydrochloride 80 mg (controlled release)	Oral	a	Novacodone	HX	MP NP	C10445	28	0	28
		a	Oxycodone Sandoz	SZ	MP NP	C10445	28	0	28
		a	OxyContin	MF	MP NP	C10445	28	0	28

[55] Schedule 1, entry for Oxycodone with naloxone in the form Tablet (controlled release) containing oxycodone hydrochloride 2.5 mg with naloxone hydrochloride 1.25 mg

omit from the column headed "Circumstances": **C4951** *substitute:* **C10445**

[56] Schedule 1, entry for Oxycodone with naloxone in the form Tablet (controlled release) containing oxycodone hydrochloride 5 mg with naloxone hydrochloride 2.5 mg

omit from the column headed "Circumstances": **C4951** *substitute:* **C10445**

[57] Schedule 1, entry for Oxycodone with naloxone in the form Tablet (controlled release) containing oxycodone hydrochloride 10 mg with naloxone hydrochloride 5 mg

omit from the column headed "Circumstances": **C4951** *substitute:* **C10445**

[58] Schedule 1, entry for Oxycodone with naloxone in the form Tablet (controlled release) containing oxycodone hydrochloride 15 mg with naloxone hydrochloride 7.5 mg

omit from the column headed "Circumstances": **C4951** *substitute:* **C10445**

[59] Schedule 1, entry for Oxycodone with naloxone in the form Tablet (controlled release) containing oxycodone hydrochloride 20 mg with naloxone hydrochloride 10 mg

omit from the column headed "Circumstances": **C4951** *substitute:* **C10445**

[60] Schedule 1, entry for Oxycodone with naloxone in the form Tablet (controlled release) containing oxycodone hydrochloride 30 mg with naloxone hydrochloride 15 mg

omit from the column headed "Circumstances": **C4951** *substitute:* **C10445**

[61] **Schedule 1, entry for Oxycodone with naloxone in the form Tablet (controlled release) containing oxycodone hydrochloride 40 mg with naloxone hydrochloride 20 mg**

omit from the column headed "Circumstances": **C4951** *substitute:* **C10445**

[62] **Schedule 1, entry for Oxycodone with naloxone in the form Tablet (controlled release) containing oxycodone hydrochloride 60 mg with naloxone hydrochloride 30 mg**

omit from the column headed "Circumstances": **C4951** *substitute:* **C10445**

[63] **Schedule 1, entry for Oxycodone with naloxone in the form Tablet (controlled release) containing oxycodone hydrochloride 80 mg with naloxone hydrochloride 40 mg**

omit from the column headed "Circumstances": **C4951** *substitute:* **C10445**

[64] **Schedule 1, omit entry for Oxytocin**

[65] **Schedule 1, entry for Perindopril in the form Tablet containing perindopril erbumine 2 mg**

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

BTC Perindopril	JB	MP NP	30	5	30	

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

Perindopril APOTEX	TY	MP NP	30	5	30	

[66] **Schedule 1, entry for Perindopril in the form Tablet containing perindopril erbumine 4 mg**

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

BTC Perindopril	JB	MP NP	30	5	30	

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

Perindopril APOTEX	TY	MP NP	30	5	30	

[67] **Schedule 1, entry for Perindopril in the form Tablet containing perindopril erbumine 8 mg**

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

BTC Perindopril	JB	MP NP	30	5	30	

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

Perindopril APOTEX	TY	MP NP	30	5	30	

[68] Schedule 1, entry for Protein formula with carbohydrate, fat, vitamins and minerals

omit:

	Oral liquid 500 mL, 8 (Nutrini Peptisorb Energy)	Oral		Nutrini Peptisorb Energy	NU	MP NP	C6890		10	5	1

[69] Schedule 1, entry for Risperidone in the form Oral solution 1 mg per mL, 100 mL

substitute:

	Oral solution 1 mg per mL, 100 mL	Oral	a	Risperdal	JC	MP NP	C4246 C5907 C6898 C6899 C10020 C10021 C10052	P6898 P6899 P10020 P10021 P10052	1	2	1
			a	Rixadone	AF	MP NP	C4246 C5907 C6898 C6899 C10020 C10021 C10052	P6898 P6899 P10020 P10021 P10052	1	2	1
			a	Risperdal	JC	MP NP	C4246 C5907 C6898 C6899 C10020 C10021 C10052	P4246 P5907	1	5	1
			a	Rixadone	AF	MP NP	C4246 C5907 C6898 C6899 C10020 C10021 C10052	P4246 P5907	1	5	1

[70] Schedule 1, entry for Sevelamer

substitute:

Sevelamer	Tablet containing sevelamer carbonate 800 mg	Oral		Sevelamer Apotex	TX	MP NP	C5491		180	5	180	
				Sevelamer Lupin	GQ	MP NP	C5491		180	5	180	
				Sevelamer Apotex	TX	MP	C5530 C9762		360	5	180	C(100)
				Sevelamer Lupin	GQ	MP	C5530 C9762		360	5	180	C(100)
	Tablet containing sevelamer hydrochloride 800 mg	Oral		Renagel	GZ	MP NP	C5491		180	5	180	
						MP	C5530 C9762		360	5	180	C(100)

[71] Schedule 1, entry for Tapentadol in each of the forms: Tablet (modified release) 50 mg (as hydrochloride); and Tablet (modified release) 100 mg (as hydrochloride)

omit from the column headed "Circumstances": **C4556** *substitute:* **C10445**

[72] **Schedule 1, entry for Tapentadol in each of the forms: Tablet (modified release) 150 mg (as hydrochloride); and Tablet (modified release) 200 mg (as hydrochloride)**

omit from the column headed "Circumstances": **C4556** *substitute:* **C10445**

[73] **Schedule 1, entry for Tapentadol in the form Tablet (modified release) 250 mg (as hydrochloride)**

omit from the column headed "Circumstances": **C4556** *substitute:* **C10445**

[74] **Schedule 1, entry for Terbinafine in the form Tablet 250 mg (as hydrochloride)**

(a) *omit:*

				a	Terbinafine GH	GQ	MP NP	C6395 C6404 C6453	P6404 P6453	42	0	42

(b) *omit:*

				a	Terbinafine GH	GQ	MP NP	C6395 C6404 C6453	P6395	42	1	42

[75] **Schedule 1, entry for Tramadol**

substitute:

Tramadol	Capsule containing tramadol hydrochloride 50 mg	Oral	a	APO-Tramadol	TX	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Chem mart Tramadol	CH	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Terry White Chemists Tramadol	TW	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Tramadol AMNEAL	EF	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Tramadol AN	EA	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Tramadol Sandoz	SZ	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			a	Tramadol SCP	CR	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20

a	Tramal	CS	MP NP	C10442 C10444	P10442	10	0	20
			PDP	C10442 C10446	P10442	10	0	20
a	Tramedo	AF	MP NP	C10442 C10444	P10442	10	0	20
			PDP	C10442 C10446	P10442	10	0	20
a	Zydol	RW	MP NP	C10442 C10444	P10442	10	0	20
			PDP	C10442 C10446	P10442	10	0	20
a	APO-Tramadol	TX	MP NP	C10442 C10444	P10444	20	0	20
			PDP	C10442 C10446	P10446	20	0	20
a	Chem mart Tramadol	CH	MP NP	C10442 C10444	P10444	20	0	20
			PDP	C10442 C10446	P10446	20	0	20
a	Terry White Chemists Tramadol	TW	MP NP	C10442 C10444	P10444	20	0	20
			PDP	C10442 C10446	P10446	20	0	20
a	Tramadol AMNEAL	EF	MP NP	C10442 C10444	P10444	20	0	20
			PDP	C10442 C10446	P10446	20	0	20
a	Tramadol AN	EA	MP NP	C10442 C10444	P10444	20	0	20
			PDP	C10442 C10446	P10446	20	0	20
a	Tramadol Sandoz	SZ	MP NP	C10442 C10444	P10444	20	0	20
			PDP	C10442 C10446	P10446	20	0	20
a	Tramadol SCP	CR	MP NP	C10442 C10444	P10444	20	0	20
			PDP	C10442 C10446	P10446	20	0	20
a	Tramal	CS	MP NP	C10442 C10444	P10444	20	0	20
			PDP	C10442 C10446	P10446	20	0	20
a	Tramedo	AF	MP NP	C10442 C10444	P10444	20	0	20
			PDP	C10442 C10446	P10446	20	0	20
a	Zydol	RW	MP NP	C10442 C10444	P10444	20	0	20
			PDP	C10442 C10446	P10446	20	0	20

Injection containing tramadol hydrochloride 100 mg in 2 mL	Injection	a	Tramadol ACT	JO	MP NP	C10444	5	0	5
					PDP	C10446	5	0	5
		a	Tramadol AN	JU	MP NP	C10444	5	0	5
					PDP	C10446	5	0	5
		a	Tramadol Sandoz	SZ	MP NP	C10444	5	0	5
					PDP	C10446	5	0	5
		a	Tramal 100	CS	MP NP	C10444	5	0	5
					PDP	C10446	5	0	5
Oral drops containing tramadol hydrochloride 100 mg per mL, 10 mL	Oral		Tramal	CS	MP NP	C10444	1	0	1
					PDP	C10446	1	0	1
Tablet (sustained release) containing tramadol hydrochloride 50 mg	Oral		Tramal SR 50	CS	MP NP	C10445	20	0	20
Tablet (sustained release) containing tramadol hydrochloride 100 mg	Oral	a	APO-Tramadol SR	TX	MP NP	C10445	20	0	20
		a	Chem mart Tramadol SR	CH	MP NP	C10445	20	0	20
		a	Terry White Chemists Tramadol SR	TW	MP NP	C10445	20	0	20
		a	Tramadol AN SR	EA	MP NP	C10445	20	0	20
		a	Tramadol Sandoz SR	SZ	MP NP	C10445	20	0	20
		a	Tramadol SR generichealth	GQ	MP NP	C10445	20	0	20
		a	Tramal SR 100	CS	MP NP	C10445	20	0	20
		a	Tramedo SR	AL	MP NP	C10445	20	0	20
		a	Zydol SR 100	RW	MP NP	C10445	20	0	20
Tablet (sustained release) containing tramadol hydrochloride 150 mg	Oral	a	APO-Tramadol SR	TX	MP NP	C10445	20	0	20
		a	Chem mart Tramadol SR	CH	MP NP	C10445	20	0	20

		a	Terry White Chemists Tramadol SR	TW	MP NP	C10445	20	0	20
		a	Tramadol AN SR	EA	MP NP	C10445	20	0	20
		a	Tramadol Sandoz SR	SZ	MP NP	C10445	20	0	20
		a	Tramadol SR generichealth	GQ	MP NP	C10445	20	0	20
		a	Tramal SR 150	CS	MP NP	C10445	20	0	20
		a	Tramedo SR	AL	MP NP	C10445	20	0	20
		a	Zydol SR 150	RW	MP NP	C10445	20	0	20
Tablet (sustained release) containing tramadol hydrochloride 200 mg	Oral	a	APO-Tramadol SR	TX	MP NP	C10445	20	0	20
		a	Chem mart Tramadol SR	CH	MP NP	C10445	20	0	20
		a	Terry White Chemists Tramadol SR	TW	MP NP	C10445	20	0	20
		a	Tramadol AN SR	EA	MP NP	C10445	20	0	20
		a	Tramadol Sandoz SR	SZ	MP NP	C10445	20	0	20
		a	Tramadol SR generichealth	GQ	MP NP	C10445	20	0	20
		a	Tramal SR 200	CS	MP NP	C10445	20	0	20
		a	Tramedo SR	AL	MP NP	C10445	20	0	20
		a	Zydol SR 200	RW	MP NP	C10445	20	0	20

[76] Schedule 1, entry for Valsartan with hydrochlorothiazide in the form Tablet 80 mg-12.5 mg

(a) *insert in the column headed "Schedule Equivalent" for the existing brand "Co-Diovan 80/12.5":* **a**

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

		a	Dilart HCT 80/12.5	AF	MP NP	C4374	28	5	28

[77] **Schedule 1, entry for Valsartan with hydrochlorothiazide in the form Tablet 160 mg-12.5 mg**

(a) *insert in the column headed "Schedule Equivalent" for the existing brand "Co-Diovan 160/12.5":* **a**

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

	a	Dilart HCT 160/12.5	AF	MP NP	C4374	28	5	28

[78] **Schedule 1, entry for Valsartan with hydrochlorothiazide in the form Tablet 160 mg-25 mg**

(a) *insert in the column headed "Schedule Equivalent" for the existing brand "Co-Diovan 160/25":* **a**

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

	a	Dilart HCT 160/25	AF	MP NP	C4374	28	5	28

[79] **Schedule 1, entry for Valsartan with hydrochlorothiazide in the form Tablet 320 mg-12.5 mg**

(a) *insert in the column headed "Schedule Equivalent" for the existing brand "Co-Diovan 320/12.5":* **a**

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

	a	Dilart HCT 320/12.5	AF	MP NP	C4361	28	5	28

[80] **Schedule 1, entry for Valsartan with hydrochlorothiazide in the form Tablet 320 mg-25 mg**

(a) *insert in the column headed "Schedule Equivalent" for the existing brand "Co-Diovan 320/25":* **a**

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

	a	Dilart HCT 320/25	AF	MP NP	C4361	28	5	28

[81] **Schedule 4, Part 1, after entry for Amino acid formula with carbohydrate, vitamins, minerals and trace elements without phenylalanine**

insert:

Amino acid formula with carbohydrate without phenylalanine	C4295			Phenylketonuria	

[82] **Schedule 4, Part 1, after entry for Amino acid formula with fat, carbohydrate, vitamins, minerals, trace elements and medium chain triglycerides**

insert:

Amino acid formula with fat, carbohydrate without methionine	C5534			Pyridoxine non-responsive homocystinuria	

[83] **Schedule 4, Part 1, after entry for Amino acid formula with fat, carbohydrate without phenylalanine**

insert:

Amino acid formula	C5533			Tyrosinaemia	

with fat, carbohydrate without phenylalanine and tyrosine					
Amino acid formula with fat, carbohydrate without valine, leucine and isoleucine	C5571			Maple syrup urine disease	

[84] Schedule 4, Part 1, entry for Bortezomib

(a) *omit:*

	C7963			Symptomatic multiple myeloma Initial PBS-subsidised treatment Patient must be newly diagnosed; AND Patient must be ineligible for high dose chemotherapy; AND Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues; AND The treatment must be in combination with a corticosteroid and melphalan or cyclophosphamide; AND Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 7963

(b) *omit:*

	C7984			Symptomatic multiple myeloma Initial PBS-subsidised treatment Patient must be newly diagnosed; AND Patient must have severe acute renal failure; AND Patient must require dialysis; OR Patient must be at high risk of requiring dialysis in the opinion of a nephrologist; AND The treatment must be in combination with a corticosteroid and/or cyclophosphamide; AND Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues; AND Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction. Details of the histological diagnosis of multiple myeloma, the name of the nephrologist who has reviewed the patient and the date of review, a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology Authority, and nomination of the disease activity parameter(s) that will be used to assess response must be documented in the patient's medical records. Disease activity parameters include current diagnostic reports of at least one of the following: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) in oligo-secretory and non-secretory myeloma patients only, the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. Magnetic Resonance Imaging (MRI) or computed tomography (CT) scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be documented in the patient's medical records for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein	Compliance with Authority Required procedures - Streamlined Authority Code 7984

				less than 10 g per L) must be documented in the patient's medical records.	

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

	C10426			Symptomatic multiple myeloma Initial PBS-subsidised treatment The condition must be newly diagnosed; AND Patient must have severe acute renal failure; AND Patient must require dialysis; OR Patient must be at high risk of requiring dialysis in the opinion of a nephrologist; AND The treatment must be in combination with a corticosteroid and/or cyclophosphamide; AND Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues; AND Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction. Details of the histological diagnosis of multiple myeloma, the name of the nephrologist who has reviewed the patient and the date of review, a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology Authority, and nomination of the disease activity parameter(s) that will be used to assess response must be documented in the patient's medical records. Disease activity parameters include current diagnostic reports of at least one of the following: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) in oligo-secretory and non-secretory myeloma patients only, the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. Magnetic Resonance Imaging (MRI) or computed tomography (CT) scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be documented in the patient's medical records for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 10426
	C10454			Multiple myeloma Triple combination therapy (bortezomib, lenalidomide and dexamethasone) The condition must be newly diagnosed; AND The treatment must be in combination with lenalidomide and dexamethasone; AND The treatment must not be in combination with PBS-subsidised thalidomide, pomalidomide or carfilzomib; AND The treatment must not be changing from dual combination therapy with lenalidomide and dexamethasone for symptomatic multiple myeloma to triple therapy with lenalidomide, bortezomib and dexamethasone; AND Patient must not receive more than 8 cycles of treatment with bortezomib under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 10454
	C10455			Symptomatic multiple myeloma Initial PBS-subsidised treatment The condition must be newly diagnosed; AND Patient must be ineligible for high dose chemotherapy; AND Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues; AND The treatment must be in combination with a corticosteroid and melphalan or cyclophosphamide; AND Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 10455

[85] Schedule 4, Part 1, entry for Budesonide with formoterol

(a) *insert in the column headed "Purposes Code" for the circumstance code "C4397":* **P4397**

(b) *insert in the column headed "Purposes Code" for the circumstance code "C7970":* **P7970**

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

	C10464	P10464		Mild asthma Patient must have asthma and require an anti-inflammatory reliever therapy; AND Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA). Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.	Compliance with Authority Required procedures - Streamlined Authority Code 10464
	C10482	P10482		Mild asthma Patient must have asthma and require an anti-inflammatory reliever therapy; AND Patient must not be on a concomitant single agent long-acting-beta-2-agonist (LABA). Patient must be aged 12 years or over. Device (inhaler) technique should be reviewed at each clinical visit and before initiating treatment with this medicine.	Compliance with Authority Required procedures - Streamlined Authority Code 10482

[86] Schedule 4, Part 1, entry for Buprenorphine

(a) *omit:*

	C4951	P4951		Chronic severe disabling pain The condition must be unresponsive to non-opioid analgesics.	

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

	C10445	P10445		Chronic severe pain The condition must require daily, continuous, long term therapy with this treatment; AND Patient must have pain directly attributable to cancer; OR Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid or other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid or other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid or other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management has been reviewed through consultation with the patient by another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed immediately prior to the first application or at least once in the past 12 months for subsequent applications. The full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management has not been reviewed through consultation with the patient by another medical practitioner to confirm the clinical need for continuing opioid analgesic treatment. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner consulted and the date of the consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia.	Compliance with Authority Required procedures - Streamlined Authority Code 10445

				Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	

[87] Schedule 4, Part 1, entry for Certolizumab pegol

insert in numerical order after existing text:

	C10431	P10431		Non-radiographic axial spondyloarthritis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction. The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.	Compliance with Written Authority Required procedures
	C10456	P10456		Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS-indication twice or more in the current treatment cycle; AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not	Compliance with Written Authority Required procedures

				conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. If the application is not made through the online system, the authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis change or recommencement of treatment PBS Authority Application - Supporting Information Form which seeks: (i) the BASDAI score confirming a reduction of 2 or more units from baseline and the C-reactive protein (CPR) level if the patient has had an adequate response to the most recent course of biological medicine; or (ii) confirmation that the patient has failed to achieve an adequate response with the most recent supply of biological medicine; or (iii) confirmation that an intolerance to the most recent supply of biological medicine had occurred; and (iv) an updated BASDAI score and CRP level if new baseline measurements are to be used for future assessments of response	
	C10458	P10458		Non-radiographic axial spondyloarthritis Grandfather treatment Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 June 2020; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that was relieved by exercise but not rest, prior to initiating non-PBS subsidised treatment with this drug for this condition; AND Patient must have had failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); prior to initiating non-PBS subsidised treatment with this drug for this condition; AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis prior to commencing non-PBS subsidised treatment with this biological medicine; AND The condition must have been diagnosed as non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, prior to having commenced non-PBS subsidised treatment with this biological medicine; AND The condition must have been sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI) prior to commencing non-PBS subsidised treatment with this biological medicine; AND The condition must have had presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent) prior to commencing non-PBS subsidised treatment with this biological medicine; AND The condition must have had BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium) prior to commencing non-PBS subsidised treatment with this biological medicine; AND The treatment must not exceed a maximum of 24 weeks with this drug under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L.	Compliance with Written Authority Required procedures

				The BASDAI score and CRP level must have been determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must have been no more than 1 month old at the time of initiating non-PBS subsidised treatment with this biological medicine for this condition. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. 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. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis Grandfathered PBS Authority Application - Supporting Information Form which seeks details of: (i) a copy of the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and (ii) a BASDAI score and CRP level that substantiates failure to achieve an adequate response to NSAIDs prior to initiating non-PBS subsidised treatment with this biological medicine for this condition; and (iii) the MRI report; and (iv) the NSAIDs trialled, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information must be included. The baseline BASDAI score and CRP level must also be documented in the patient's medical records.	
	C10459	P10459		Non-radiographic axial spondyloarthritis Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 18 to 20 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 to 20 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 to 20 weeks treatment; AND The treatment must provide no more than the balance of up to 20 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.	Compliance with Written Authority Required procedures
	C10468	P10468		Non-radiographic axial spondyloarthritis Initial treatment - Initial 1 (New patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND	Compliance with Written Authority Required procedures

				The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis initial PBS Authority Application - Supporting Information Form which seeks details of: (i) the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline C-reactive protein (CRP) level; and (iv) a completed Exercise Program Self Certification Form included in the supporting information form; and (v) the MRI report; and (vi) the NSAIDs trialled, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information must be included. The baseline BASDAI score and CRP level must also be documented in the patient's medical records.	
	C10480	P10480		Non-radiographic axial spondyloarthritis Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND	Compliance with Written Authority Required procedures

				Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The following must be stated in this application and documented in the patient's medical records: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.	
	C10489	P10489		Non-radiographic axial spondyloarthritis Continuing treatment or Grandfather patient - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Continuing treatment restriction to complete 24 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Grandfathered treatment restriction to complete 24 weeks treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the continuing treatment restriction or the grandfather restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.	Compliance with Written Authority Required procedures

[88] Schedule 4, Part 1, after entry for Cobimetinib

insert:

Codeine	C10442	P10442		Severe pain The treatment must be for short term therapy of acute severe pain; AND Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance.	
	C10444	P10444		Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other	

				non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management and clinical need for continuing opioid treatment has been reviewed and confirmed through consultation with the patient by another medical practitioner. The review must have been in the past 12 months and the full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iv) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management and need for continuing opioid treatment has not been reviewed through consultation with the patient by another medical practitioner. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner and the date of the planned consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	
	C10446	P10446		Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance.	
	C10479	P10479		Cough The treatment must be for cough suppression.	

[89] Schedule 4, Part 1, entry for Codeine with paracetamol

substitute:

Codeine with paracetamol	C10442	P10442		Severe pain The treatment must be for short term therapy of acute severe pain; AND Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance.	
	C10444	P10444		Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR	

				Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management and clinical need for continuing opioid treatment has been reviewed and confirmed through consultation with the patient by another medical practitioner. The review must have been in the past 12 months and the full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iv) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management and need for continuing opioid treatment has not been reviewed through consultation with the patient by another medical practitioner. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner and the date of the planned consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	
	C10446	P10446		Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance.	

[90] Schedule 4, Part 1, entry for Fentanyl

(a) *omit:*

	C4952			Chronic severe disabling pain The condition must be unresponsive to non-opioid analgesics.	

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

	C10441			Chronic severe disabling pain The condition must require daily, continuous, long term therapy with this treatment; AND Patient must not be opioid naive; AND Patient must have pain directly attributable to cancer; OR Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid and other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid and other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management has been reviewed through consultation with the patient by	Compliance with Authority Required procedures - Streamlined Authority Code 10441

				another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed immediately prior to the first application or at least once in the past 12 months for subsequent applications. The full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management has not been reviewed through consultation with the patient by another medical practitioner to confirm the clinical need for continuing opioid analgesic treatment. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner consulted and the date of the consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	

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

(a) *omit:*

	C8155	P8155		Non-radiographic axial spondyloarthritis Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An adequate response to therapy with this drug is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 1-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. When a patient has either failed or ceased to respond to treatment with this drug for this condition twice, they must have, at a minimum, a 5-year break in PBS-subsidised treatment with this drug for this condition before they are eligible to re-commence under the Initial 1 - New patient or recommencement after a break of more than 5 years. The 5-year break is measured from the approved date of the last prescription for PBS-subsidised treatment with this drug for this condition to the date of the first application for initial treatment under the Initial 1 restriction. A patient who has failed treatment with this drug for this condition fewer than twice and who has a break in therapy of less than 5 years may re-commence a further course of treatment with this drug for this condition under the Initial 2 - Re-commencement of treatment after a break of less than 5 years. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis PBS Authority Application - Supporting Information including evidence of adequate response to therapy with PBS-subsidised golimumab.	Compliance with Written Authority Required procedures
	C8201	P8201		Non-radiographic axial spondyloarthritis Initial treatment 1 and 2 - balance of supply Patient must have received insufficient therapy with this drug under the Initial 1 (New patients or recommencement after a break of more than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug under the Initial 2 (Re-commencement of treatment after a	Compliance with Authority Required procedures

				break of less than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.	
	C8223	P8223		Non-radiographic axial spondyloarthritis Initial treatment 2 (Re-commencement of treatment after a break of less than 5 years) Patient must have a documented history of non-radiographic axial spondyloarthritis; AND Patient must have received prior PBS-subsidised treatment with this drug for this condition within the last five years; AND Patient must not have failed PBS-subsidised treatment with this drug for this condition more than once within the last five years; AND The treatment must not exceed a maximum of 16 weeks with this drug under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An application for Initial 2 treatment must be accompanied by BASDAI and CRP results of the most recent course of treatment with this drug for this condition within the last 5 years to demonstrate a response to treatment. The results must be conducted following a minimum of 12 weeks of treatment. When a patient has either failed or ceased to respond to treatment with this drug for this condition twice, they must have, at a minimum, a 5-year break in PBS-subsidised treatment with this drug for this condition before they are eligible to re-commence under the Initial 1 - New patient or recommencement after a break of more than 5 years. The 5-year break is measured from the approved date of the last prescription for PBS-subsidised treatment with this drug for this condition to the date of the first application for initial treatment under the Initial 1 restriction. A patient who has failed treatment with this drug for this condition fewer than twice and who has a break in therapy of less than 5 years may re-commence a further course of treatment with this drug for this condition under the Initial 2 - Re-commencement of treatment after a break of less than 5 years. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis PBS Authority Application - Supporting Information Form including: a completed BASDAI Assessment Form; and a copy of C-reactive protein (CRP) test result	Compliance with Written Authority Required procedures
	C8224	P8224		Non-radiographic axial spondyloarthritis Initial treatment 3 (grandfathered patient) Patient must have previously received non-PBS subsidised therapy with this drug for this condition prior to 1 December 2018; AND Patient must have demonstrated an adequate response to non-PBS subsidised treatment with this drug for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that was relieved by exercise but not rest, prior to initiating non-PBS subsidised treatment with this drug for this condition; AND Patient must have had failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); prior to initiating non-PBS subsidised treatment with this drug for this condition; AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must have been sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance	Compliance with Written Authority Required procedures

				Imaging (MRI); AND The condition must have had presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have had BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 24 weeks with this drug under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non PBS subsidised treatment with this drug for this condition: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initiating non-PBS subsidised treatment with this drug for this condition. CRP measurement must be provided with the initial treatment application and must be no more than 1 month old at the time of initiating non-PBS subsidised treatment with this drug for this condition. The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. An adequate response to therapy with this drug is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 1-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. 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. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis Grandfathered PBS Authority Application - Supporting Information Form which must include the following: (i) a copy of the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and (ii) evidence of failure to achieve an adequate response to NSAIDs prior to initiating non-PBS subsidised golimumab for this condition ; and (iii) evidence of an adequate response to therapy with non-PBS subsidised golimumab for this condition following a minimum of 12 weeks of treatment with this drug for this condition; and (iv) a copy of the MRI report; and (v) details of the NSAIDs trialled, their doses and duration of treatment or the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication according to the relevant TGA-approved Product Information.	
	C8225	P8225		Non-radiographic axial spondyloarthritis Continuing and Grandfathered treatment - balance of supply Patient must have received insufficient therapy with this drug under the Initial 3 (grandfathered patient) restriction to complete	Compliance with Authority Required

				24 weeks of treatment; OR Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.	procedures
	C8229	P8229		Non-radiographic axial spondyloarthritis Initial treatment 1 (New patients or recommencement after a break of more than 5 years) Patient must not have received PBS-subsidised treatment with this drug for this condition in the last 5 years or more; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 16 weeks with this drug under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. The BASDAI must be no more than 1 month old at the time of initial application. CRP measure must be provided with the initial treatment application and must be no more than 1 month old at the time of application. The assessment of the patient's response to the initial course of treatment must be made following a minimum of 12 weeks of treatment and submitted no later than 4 weeks from the cessation of that treatment course. If the response assessment is not submitted within these timeframes, the patient will be deemed to have failed this course of treatment. When a patient has either failed or ceased to respond to treatment with this drug for this condition twice, they must have, at a minimum, a 5-year break in PBS-subsidised treatment with this drug for this condition before they are eligible to re-commence under the Initial 1 - New patient or recommencement after a break of more than 5 years. The 5-year break is measured from the approved date of the last prescription for PBS-subsidised treatment with this drug for	Compliance with Written Authority Required procedures

				this condition to the date of the first application for initial treatment under the Initial 1 restriction. A patient who has failed treatment with this drug for this condition fewer than twice and who has a break in therapy of less than 5 years may re-commence a further course of treatment with this drug for this condition under the Initial 2 - Re-commencement of treatment after a break of less than 5 years. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis initial PBS Authority Application - Supporting Information Form which must include the following: (i) a copy of the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and (ii) a completed BASDAI Assessment Form; and (iii) a copy of C-reactive protein (CRP) test result which must not be more than 1 month old at the time of application; and (iv) a completed Exercise Program Self Certification Form included in the supporting information form; and (v) a copy of the MRI report; and (vi) details of the NSAIDs trialled, their doses and duration of treatment or the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication according to the relevant TGA-approved Product Information	

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

	C10434	P10434		Non-radiographic axial spondyloarthritis Continuing treatment - balance of supply Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks of treatment; AND The treatment must provide no more than the balance of up to 24 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.	Compliance with Authority Required procedures
	C10435	P10435		Non-radiographic axial spondyloarthritis Initial treatment - Initial 1 (New patient) Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 16 weeks with this drug under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialled, their doses and duration of treatment.	Compliance with Written Authority Required procedures

				If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must be no more than 4 weeks old at the time of initial application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis initial PBS Authority Application - Supporting Information Form which seeks details of: (i) the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iii) a baseline C-reactive protein (CRP) level; and (iv) a completed Exercise Program Self Certification Form included in the supporting information form; and (v) the MRI report; and (vi) the NSAIDs trialled, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information must be included. The baseline BASDAI score and CRP level must also be documented in the patient's medical records.	
	C10436	P10436		Non-radiographic axial spondyloarthritis Initial 1 (New patient), Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 16 weeks treatment; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 16 weeks treatment; AND The treatment must provide no more than the balance of up to 16 weeks treatment. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.	Compliance with Authority Required procedures
	C10461	P10461		Non-radiographic axial spondyloarthritis Continuing treatment Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND	Compliance with Written Authority Required procedures

				Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. If the requirement to demonstrate an elevated CRP level could not be met under an initial treatment restriction, a reduction in the BASDAI score from baseline will suffice for the purposes of administering this continuing treatment restriction. The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.	
	C10490	P10490		Non-radiographic axial spondyloarthritis Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; AND Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; AND Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND The condition must have presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND The treatment must not exceed a maximum of 16 weeks duration under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The following must be stated in this application and documented in the patient's medical records: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.	Compliance with Written Authority Required procedures
	C10491	P10491		Non-radiographic axial spondyloarthritis Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years) Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment	Compliance with Written Authority Required

				cycle; AND Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with biological medicines more than three times for this PBS-indication during the current treatment cycle; AND The treatment must not exceed a maximum of 16 weeks with this drug under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. Patient must not have failed PBS-subsidised therapy with this biological medicine for this PBS-indication twice or more in the current treatment cycle. An application for Initial 2 treatment must indicate whether the patient has demonstrated an adequate response (an absence of treatment failure), failed or experienced an intolerance to the most recent supply of biological medicine treatment. A new baseline Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score and C-reactive protein (CRP) level may be provided at the time of this application. An adequate response to therapy with this biological medicine is defined as a reduction from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 0-10) and 1 of the following: (a) a CRP measurement no greater than 10 mg per L; or (b) a CRP measurement reduced by at least 20% from baseline. The assessment of the patient's response to the most recent supply of biological medicine must be conducted following a minimum of 12 weeks of treatment. BASDAI scores and CRP levels must be documented in the patient's medical records. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. If the application is not made through the online system, the authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis change or recommencement of treatment PBS Authority Application - Supporting Information Form which seeks: (i) the BASDAI score confirming a reduction of 2 or more units from baseline and the C-reactive protein (CPR) level if the patient has had an adequate response to the most recent course of biological medicine; or (ii) confirmation that the patient has failed to achieve an adequate response with the most recent supply of biological medicine; or (iii) confirmation that an intolerance to the most recent supply of biological medicine had occurred; and (iv) an updated BASDAI score and CRP level if new baseline measurements are to be used for future assessments of response	procedures

[92] Schedule 4, Part 1, entry for Hydromorphone

substitute:

Hydromorphone	C10439	P10439		Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid and other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid and other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management and clinical need for continuing opioid treatment has been reviewed and confirmed through consultation with the patient by another medical practitioner. The review must have been in the past 12 months and the full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iv) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management and need for continuing opioid treatment has not been reviewed through consultation with the patient by another medical practitioner. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner and the date of the planned consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	
	C10440	P10440		Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid and other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid and other opioid analgesics due to contraindications, adverse effects or intolerance.	
	C10448			Chronic severe pain The condition must require daily, continuous, long term therapy with this treatment; AND Patient must not be opioid naive; AND Patient must have pain directly attributable to cancer; OR Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid and other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid and other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management has been reviewed through consultation with the patient by	Compliance with Authority Required procedures - Streamlined Authority Code 10448

				another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed immediately prior to the first application or at least once in the past 12 months for subsequent applications. The full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management has not been reviewed through consultation with the patient by another medical practitioner to confirm the clinical need for continuing opioid analgesic treatment. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner consulted and the date of the consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	
	C10451	P10451		Severe pain The treatment must be for short term therapy of acute severe pain; AND Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid and other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid and other opioid analgesics due to contraindications, adverse effects or intolerance.	

[93] Schedule 4, Part 1, entry for Methadone

(a) *omit:*

	C4953			Severe disabling pain The condition must be unresponsive to non-opioid analgesics.	

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

	C10441			Chronic severe disabling pain The condition must require daily, continuous, long term therapy with this treatment; AND Patient must not be opioid naive; AND Patient must have pain directly attributable to cancer; OR Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid and other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid and other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management has been reviewed through consultation with the patient by another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed immediately prior to the first application or at least once in the past 12 months for subsequent applications. The full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management has not been reviewed through consultation with the patient by another medical practitioner to confirm the clinical need for continuing opioid analgesic treatment. A review	Compliance with Authority Required procedures - Streamlined Authority Code 10441

				must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner consulted and the date of the consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	

[94] Schedule 4, Part 1, entry for Morphine

(a) *omit:*

	C4556			Chronic severe disabling pain The condition must be unresponsive to non-opioid analgesics.	
	C4900	P4900		Chronic severe disabling pain The condition must be due to cancer; AND The condition must be unresponsive to non-opioid analgesics.	Compliance with Authority Required procedures
	C4926			Severe disabling pain The condition must be unresponsive to non-opioid analgesics.	
	C4959			Severe disabling pain The condition must be unresponsive to non-opioid analgesics.	
	C4960	P4960		Severe disabling pain The condition must be due to cancer; AND The condition must be unresponsive to non-opioid analgesics.	

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

	C10439	P10439		Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid and other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid and other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management and clinical need for continuing opioid treatment has been reviewed and confirmed through consultation with the patient by another medical practitioner. The review must have been in the past 12 months and the full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iv) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management and need for continuing opioid treatment has not been reviewed through consultation with the patient by another medical practitioner. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner and the date of the planned consultation are to be provided at the time of the application.	

				Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	
	C10440	P10440		Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid and other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid and other opioid analgesics due to contraindications, adverse effects or intolerance.	
	C10445			Chronic severe pain The condition must require daily, continuous, long term therapy with this treatment; AND Patient must have pain directly attributable to cancer; OR Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid or other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid or other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid or other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management has been reviewed through consultation with the patient by another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed immediately prior to the first application or at least once in the past 12 months for subsequent applications. The full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management has not been reviewed through consultation with the patient by another medical practitioner to confirm the clinical need for continuing opioid analgesic treatment. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner consulted and the date of the consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	Compliance with Authority Required procedures - Streamlined Authority Code 10445
	C10451	P10451		Severe pain The treatment must be for short term therapy of acute severe pain; AND Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid and other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid and other opioid analgesics due to contraindications, adverse effects or intolerance.	
	C10466	P10466		Chronic severe disabling pain The condition must require daily, continuous, long term therapy with this treatment; AND	Compliance with Authority Required

				Patient must have pain directly attributable to cancer; OR Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid or other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid or other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid or other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management has been reviewed through consultation with the patient by another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed immediately prior to the first application or at least once in the past 12 months for subsequent applications. The full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management has not been reviewed through consultation with the patient by another medical practitioner to confirm the clinical need for continuing opioid analgesic treatment. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner consulted and the date of the consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	procedures
	C10472			Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid and other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid and other opioid analgesics due to contraindications, adverse effects or intolerance; OR The treatment must be part of pre-operative care; OR The treatment must be used as an analgesic adjunct in general anaesthesia. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management and clinical need for continuing opioid treatment has been reviewed and confirmed through consultation with the patient by another medical practitioner. The review must have been in the past 12 months and the full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iv) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management and need for continuing opioid treatment has not been reviewed through consultation with the patient by another medical practitioner. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner and the date of the planned consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities	

				system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	
	C10478			Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid and other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid and other opioid analgesics due to contraindications, adverse effects or intolerance; OR The treatment must be part of pre-operative care; OR The treatment must be used as an analgesic adjunct in general anaesthesia.	
	C10486	P10486		Cancer pain Patient must have pain directly attributable to cancer; AND Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid and other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid and other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management has been reviewed through consultation with the patient by another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed immediately prior to the first application or at least once in the past 12 months for subsequent applications. The full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management has not been reviewed through consultation with the patient by another medical practitioner to confirm the clinical need for continuing opioid analgesic treatment. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner consulted and the date of the consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	
	C10487	P10487		Chronic severe disabling pain The condition must require daily, continuous, long term therapy with this treatment; AND Patient must have pain directly attributable to cancer; OR Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid or other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid or other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid or other opioid analgesics due to contraindications, adverse effects or intolerance.	Compliance with Authority Required procedures

[95] Schedule 4, Part 1, entry for Oxycodone

substitute:

Oxycodone	C10442	P10442		Severe pain The treatment must be for short term therapy of acute severe pain; AND Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance.	
	C10444	P10444		Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management and clinical need for continuing opioid treatment has been reviewed and confirmed through consultation with the patient by another medical practitioner. The review must have been in the past 12 months and the full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iv) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management and need for continuing opioid treatment has not been reviewed through consultation with the patient by another medical practitioner. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner and the date of the planned consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	
	C10445			Chronic severe pain The condition must require daily, continuous, long term therapy with this treatment; AND Patient must have pain directly attributable to cancer; OR Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid or other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid or other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid or other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management has been reviewed through consultation with the patient by another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed immediately prior to the first application or at least once in the past 12 months for subsequent applications. The full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or	Compliance with Authority Required procedures - Streamlined Authority Code 10445

				(iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management has not been reviewed through consultation with the patient by another medical practitioner to confirm the clinical need for continuing opioid analgesic treatment. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner consulted and the date of the consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	
	C10446	P10446		Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance.	
	C10477			Severe pain Patient must have pain directly attributable to cancer; OR The treatment must be for post-operative pain following a major operative procedure; AND Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management and clinical need for continuing opioid treatment has been reviewed and confirmed through consultation with the patient by another medical practitioner. The review must have been in the past 12 months and the full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iv) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management and need for continuing opioid treatment has not been reviewed through consultation with the patient by another medical practitioner. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner and the date of the planned consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	
	C10485			Severe pain The treatment must be for post-operative pain following a major operative procedure; AND Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR	

				The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance.	

[96] Schedule 4, Part 1, entry for Oxycodone with naloxone

substitute:

Oxycodone with naloxone	C10445			Chronic severe pain The condition must require daily, continuous, long term therapy with this treatment; AND Patient must have pain directly attributable to cancer; OR Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid or other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid or other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid or other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management has been reviewed through consultation with the patient by another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed immediately prior to the first application or at least once in the past 12 months for subsequent applications. The full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management has not been reviewed through consultation with the patient by another medical practitioner to confirm the clinical need for continuing opioid analgesic treatment. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner consulted and the date of the consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	Compliance with Authority Required procedures - Streamlined Authority Code 10445

[97] Schedule 4, Part 1, entry for Tapentadol

substitute:

Tapentadol	C10445			Chronic severe pain The condition must require daily, continuous, long term therapy with this treatment; AND Patient must have pain directly attributable to cancer; OR Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid or other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid or other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid or other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or	Compliance with Authority Required procedures - Streamlined Authority Code 10445

				has exceeded 12 months and the patient's pain management has been reviewed through consultation with the patient by another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed immediately prior to the first application or at least once in the past 12 months for subsequent applications. The full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management has not been reviewed through consultation with the patient by another medical practitioner to confirm the clinical need for continuing opioid analgesic treatment. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner consulted and the date of the consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	

[98] Schedule 4, Part 1, entry for Tramadol

substitute:

Tramadol	C10442	P10442		Severe pain The treatment must be for short term therapy of acute severe pain; AND Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance.	
	C10444	P10444		Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management and clinical need for continuing opioid treatment has been reviewed and confirmed through consultation with the patient by another medical practitioner. The review must have been in the past 12 months and the full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iv) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management and need for continuing opioid treatment has not been reviewed through consultation with the patient by another medical practitioner. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner and the date of the planned consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month	

				treatment and up to 2 repeats).	
	C10445			Chronic severe pain The condition must require daily, continuous, long term therapy with this treatment; AND Patient must have pain directly attributable to cancer; OR Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid or other opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid or other opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use non-opioid or other opioid analgesics due to contraindications, adverse effects or intolerance. Authorities for increased maximum quantities and/or repeats must only be considered for: (i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or (ii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment will or has exceeded 12 months and the patient's pain management has been reviewed through consultation with the patient by another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed immediately prior to the first application or at least once in the past 12 months for subsequent applications. The full name of the medical practitioner consulted and the date of the most recent consultation are to be provided at the time of each application; or (iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's pain management has not been reviewed through consultation with the patient by another medical practitioner to confirm the clinical need for continuing opioid analgesic treatment. A review must have been planned to take place within 3 months from the date of this application. The full name of the medical practitioner consulted and the date of the consultation are to be provided at the time of the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and up to 2 repeats).	Compliance with Authority Required procedures - Streamlined Authority Code 10445
	C10446	P10446		Severe pain Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of other non-opioid analgesics; OR The condition must be such that maximum tolerated doses of non-opioid analgesics would provide inadequate management of pain relief; OR Patient must be unable to use other non-opioid analgesics due to contraindications, adverse effects or intolerance.	

[99] Schedule 5, entry for Levodopa with carbidopa *[GRP-22957]*

omit:

		Tablet (modified release) 200 mg-50 mg	Oral	Carbidopa and Levodopa Extended-release Tablets

[100] Schedule 5, entry for Perindopril in the form Tablet containing perindopril erbumine 4 mg *[GRP-15442]*

(a) *insert in alphabetical order in the column headed "Brand":* **BTC Perindopril**

(b) *omit from the column headed "Brand":* **Perindopril Actavis 4**

(c) *insert in alphabetical order in the column headed "Brand":* **Perindopril Actavis 4**

(d) *insert in alphabetical order in the column headed "Brand":* **Perindopril APOTEX**

[101] **Schedule 5, entry for Perindopril in the form Tablet containing perindopril erbumine 8 mg *[GRP-15525]***

(a) *insert in alphabetical order in the column headed "Brand":* **BTC Perindopril**

(b) *omit from the column headed "Brand":* **Perindopril Actavis 8**

(c) *insert in alphabetical order in the column headed "Brand":* **Perindopril Actavis 8**

(d) *insert in alphabetical order in the column headed "Brand":* **Perindopril APOTEX**

[102] **Schedule 5, entry for Perindopril in the form Tablet containing perindopril erbumine 2 mg *[GRP-15965]***

(a) *insert in alphabetical order in the column headed "Brand":* **BTC Perindopril**

(b) *omit from the column headed "Brand":* **Perindopril Actavis 2**

(c) *insert in alphabetical order in the column headed "Brand":* **Perindopril Actavis 2**

(d) *insert in alphabetical order in the column headed "Brand":* **Perindopril APOTEX**

[103] **Schedule 5, entry for Sevelamer in the form Tablet containing sevelamer carbonate 800 mg *[GRP-23578]***

insert in alphabetical order in the column headed "Brand": **Sevelamer Lupin**

[104] **Schedule 6**

omit table and substitute:

Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic

Listed drug	Form	Manner of administration
Abatacept	Injection 125 mg in 1 mL single dose autoinjector	Injection
Abatacept	Injection 125 mg in 1 mL single dose pre-filled syringe	Injection
Abatacept	Powder for I.V. infusion 250 mg	Injection
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe, 6	Injection
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen, 4	Injection
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen, 6	Injection
Ambrisentan	Tablet 5 mg	Oral
Ambrisentan	Tablet 10 mg	Oral
Baricitinib	Tablet 2 mg	Oral

Baricitinib	Tablet 4 mg	Oral
Benralizumab	Injection 30 mg in 1 mL single dose pre-filled syringe	Injection
Benralizumab	Injection 30 mg in 1 mL single dose pre-filled pen	Injection
Bosentan	Tablet 62.5 mg (as monohydrate)	Oral
Bosentan	Tablet 125 mg (as monohydrate)	Oral
Certolizumab pegol	Injection 200 mg in 1 mL single use pre-filled syringe	Injection
Certolizumab pegol	Solution for injection 200 mg in 1 mL pre-filled pen	Injection
Dornase alfa	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	Inhalation
Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium)	Injection
Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL	Injection
Epoprostenol	Powder for I.V. infusion 1.5 mg (as sodium)	Injection
Epoprostenol	Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL	Injection
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection
Golimumab	Injection 50 mg in 0.5 mL single use pre-filled pen	Injection
Golimumab	Injection 50 mg in 0.5 mL single use pre-filled syringe	Injection
Golimumab	Injection 100 mg in 1 mL single use pre-filled pen	Injection
Guselkumab	Injection 100 mg in 1 mL single use pre-filled syringe	Injection
Iloprost	Solution for inhalation 20 micrograms (as trometamol) in 2 mL	Inhalation
Infliximab	Powder for I.V. infusion 100 mg	Injection
Ivacaftor	Sachet containing granules 50 mg	Oral
Ivacaftor	Sachet containing granules 75 mg	Oral

Ivacaftor	Tablet 150 mg	Oral
Ixekizumab	Injection 80 mg in 1 mL single dose pre-filled pen	Injection
Lenalidomide	Capsule 5 mg	Oral
Lenalidomide	Capsule 10 mg	Oral
Lenalidomide	Capsule 15 mg	Oral
Lenalidomide	Capsule 25 mg	Oral
Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 100 mg and ivacaftor 125 mg	Oral
Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 150 mg and ivacaftor 188 mg	Oral
Lumacaftor with ivacaftor	Tablet containing lumacaftor 100 mg with ivacaftor 125 mg	Oral
Lumacaftor with ivacaftor	Tablet containing lumacaftor 200 mg with ivacaftor 125 mg	Oral
Macitentan	Tablet 10 mg	Oral
Mannitol	Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers	Inhalation by mouth
Mepolizumab	Powder for injection 100 mg	Injection
Mepolizumab	Injection 100 mg in 1 mL single dose pre-filled pen	Injection
Montelukast	Tablet, chewable, 4 mg (as sodium)	Oral
Montelukast	Tablet, chewable, 5 mg (as sodium)	Oral
Nintedanib	Capsule 100 mg	Oral
Nintedanib	Capsule 150 mg	Oral
Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection
Omalizumab	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection
Pirfenidone	Capsule 267 mg	Oral
Pirfenidone	Tablet 267 mg	Oral
Pirfenidone	Tablet 801mg	Oral

Pomalidomide	Capsule 3 mg	Oral
Pomalidomide	Capsule 4 mg	Oral
Riociguat	Tablet 500 micrograms	Oral
Riociguat	Tablet 1 mg	Oral
Riociguat	Tablet 1.5 mg	Oral
Riociguat	Tablet 2 mg	Oral
Riociguat	Tablet 2.5 mg	Oral
Risankizumab	Injection 75 mg in 0.83 mL pre-filled syringe	Injection
Rituximab	Solution for I.V. infusion 500 mg in 50 mL	Injection
Secukinumab	Injection 150 mg in 1 mL pre-filled pen	Injection
Sildenafil	Tablet 20 mg (as citrate)	Oral
Somatropin	Injection 0.4 mg (1.2 i.u.) with diluent in single use syringe (without preservative)	Injection
Somatropin	Injection 0.6 mg (1.8 i.u.) with diluent in single use syringe (without preservative)	Injection
Somatropin	Injection 0.8 mg (2.4 i.u.) with diluent in single use syringe (without preservative)	Injection
Somatropin	Injection 1 mg (3 i.u.) with diluent in single use syringe (without preservative)	Injection
Somatropin	Injection 1.2 mg (3.6 i.u.) with diluent in single use syringe (without preservative)	Injection
Somatropin	Injection 1.4 mg (4.2 i.u.) with diluent in single use syringe (without preservative)	Injection
Somatropin	Injection 1.6 mg (4.8 i.u.) with diluent in single use syringe (without preservative)	Injection
Somatropin	Injection 1.8 mg (5.4 i.u.) with diluent in single use syringe (without preservative)	Injection
Somatropin	Injection 2 mg (6 i.u.) with diluent in single use syringe (without preservative)	Injection
Somatropin	Injection 4 mg (12 i.u.) vial with diluent (with preservative)	Injection

Somatropin	Injection 18 i.u. (6 mg) cartridge with 3.15 mL diluent (with preservative)	Injection
Somatropin	Injection 72 i.u. (24 mg) cartridge with 3.15 mL diluent (with preservative)	Injection
Somatropin	Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative)	Injection
Somatropin	Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative)	Injection
Somatropin	Injection 36 i.u. (12 mg) cartridge with 3.15 mL diluent (with preservative)	Injection
Somatropin	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen	Injection
Somatropin	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)	Injection
Somatropin	Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative)	Injection
Somatropin	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)	Injection
Somatropin	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen	Injection
Somatropin	Solution for injection 10 mg (30 i.u.) in 2 mL cartridge (with preservative)	Injection
Somatropin	Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative)	Injection
Somatropin	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)	Injection
Somatropin	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen	Injection
Somatropin	Solution for injection 20 mg (60 i.u.) in 2.5 mL cartridge (with preservative)	Injection
Tadalafil	Tablet 20 mg	Oral
Tezacaftor with ivacaftor and ivacaftor	Pack containing 28 tablets tezacaftor 100 mg with ivacaftor 150 mg and 28 tablets ivacaftor 150 mg	Oral

Tildrakizumab	Injection 100 mg in 1 mL single dose pre-filled syringe	Injection
Tocilizumab	Concentrate for injection 80 mg in 4 mL	Injection
Tocilizumab	Concentrate for injection 200 mg in 10 mL	Injection
Tocilizumab	Concentrate for injection 400 mg in 20 mL	Injection
Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled pen	Injection
Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled syringe	Injection
Tofacitinib	Tablet 5 mg	Oral
Ustekinumab	Injection 45 mg in 0.5 mL	Injection
Ustekinumab	Solution for I.V. infusion 130 mg in 26 mL	Injection
Vedolizumab	Powder for injection 300 mg	Injection