

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 29<sup>th</sup> 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:								
	id formula with rate without inine	Tablets containing 0.92 g protein, Oral 462 (PKU Easy Tablet)	PKU Easy Tablet	ОН	MP NP	C4295	4	5	1
[2]		l, after entry for Amino acid formula v powder 400 g (Neocate Junior)	with fat, carbohydrate	, vita	amins, m	inerals, trace eler	nents and medium	chain	triglycerides in the
	id formula with hydrate without ne	Tablets containing 0.91 g protein, Oral 462 (HCU Easy Tablet)	HCU Easy Tablet	OH	MP NP	C5534	5	5	1
[3]	Schedule 1	I, after entry for Amino acid formula	with fat, carbohydrate	with	out phei	nylalanine			
fat, carbo	id formula with hydrate without nine and tyrosine	Tablets containing 0.91 g protein, Oral 462 (TYR Easy Tablet) e	TYR Easy Tablet	ОН	MP NP	C5533	4	5	1
	id formula with hydrate without ucine and	Tablets containing 0.91 g protein, Oral 462 (MSUD Easy Tablet)	MSUD Easy Tablet	ОН	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]	Sche	dule 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]	Sche	dule 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			
Insti	<b>(C)</b> rument N	insert in numerical order in the column headed "Circumstances": <b>C10426 C10454 C10455</b> Imber PB 42 of 2020 3			

# [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

	Pressurised inhalation containing Inhalation by budesonide 100 micrograms with mouth		Symbicort Rapihaler 00/3	AP	MP NP	C4397 C10482	P10482	2	2	1
	formoterol fumarate dihydrate 3 micrograms per dose, 120 doses	I	00/3		MP NP	C4397 C10482	P4397	2	5	1
	Schedule 1, entry for Budesonide with formoter 200 micrograms with formoterol fumarate dihyd						n actuated c	levice co	ontaining	budesonide
	substitute:									
	Powder for oral inhalation in Inhalation by	a D	DuoResp Spiromax	ΤВ	MP NP	C7970 C10464	P10464	1	2	1
	breath actuated device containing mouth budesonide 200 micrograms with formoterol fumarate dihydrate		Symbicort Turbuhaler 200/6	AP	MP NP	C7970 C10464	P10464	1	2	1
	6 micrograms per dose, 120 doses	a [	DuoResp Spiromax	ΤВ	MP NP	C7970 C10464	P7970	1	5	1
			Symbicort Turbuhaler 200/6	AP	MP NP	C7970 C10464	P7970	1	5	1
	Schedule 1, entry for Buprenorphine in the form	n Trans	dermal patch 5	mg	[Maximu	ım Quantity: 2;	Number of	Repeats	s: 0]	
	(a) omit from the column headed "Circumstances" (a	all insta	nces): <b>C4951</b>							
	(b) insert in numerical order in the column headed "	Circums	tances" (all insta	nces	): C1044	5				
	(c) omit from the column headed "Purposes" (all ins	stances):	P4951	sı	ubstitute:	P10445				
<b>D]</b>	Schedule 1, entry for Buprenorphine in the form	n Trans	dermal patch 5	mg	[Maximu	ım Quantity: 4;	Number of	Repeats	s: 2]	
	(a) omit from the column headed "Circumstances" (a	all insta	nces): <b>C4951</b>							
	(b) <i>insert in numerical order in the column headed "</i>	Circums	tances" (all insta	nces	): C1044	5				
1]	<ul> <li>Schedule 1, entry for Buprenorphine in the form</li> <li>(a) omit from the column headed "Circumstances" (a</li> <li>(b) insert in numerical order in the column headed "</li> </ul>	all insta	nces): <b>C4951</b>				2; Number o	of Repeat	ts: 0]	
	(C) omit from the column headed "Purposes" (all ins				ubstitute:					
2]	Schedule 1, entry for Buprenorphine in the form	<i>,</i>					l: Number o	f Repeat	ts: 21	
-1	(a) omit from the column headed "Circumstances" (a		-	<b>U</b> III	9 [	an quanty 7	, number u			
_	Vi children children children (		····/· - ••••							

- [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

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 Injection mL pre-filled pen	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	$\begin{array}{c} C8626 \ C8627 \\ C8679 \ C8705 \\ C8706 \ C8753 \\ C9063 \ C9073 \\ C9074 \ C9105 \\ C9183 \ C9185 \\ C9430 \ C9431 \\ C9442 \ C9537 \\ C9610 \ C9625 \\ C10431 \ C10456 \\ C10458 \ C10459 \\ C10468 \ C10480 \\ C10489 \end{array}$	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				
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 14 0 14 C5687 C5688 C5689 C5722 C5780	
--	--

#### [25] Schedule 1, entry for Codeine

Codeine	Tablet containing codeine phosphate hemihydrate 30 mg	Oral	Aspen Pharma Pty AS Ltd	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

Codeine with paracetamol	Tablet containing codeine phosphate hemihydrate 30 mg	Oral	а	APO- Paracetamol/Codei	тх	MP NP	C10442 C10444	P10442	10	0	20
	with paracetamol 500 mg			ne 500/30		PDP	C10442 C10446	P10442	10	0	20
			а	Codalgin Forte	AF	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			а	Codapane Forte 500/30	AL	MP NP	C10442 C10444	P10442	10	0	20
				500/30		PDP	C10442 C10446	P10442	10	0	20
			а	Comfarol Forte	SZ	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			а	Panadeine Forte	SW	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			а	Paracetamol/Codei ne GH 500/30	GQ	MP NP	C10442 C10444	P10442	10	0	20
				THE GH 500/30		PDP	C10442 C10446	P10442	10	0	20
			а	Prodeine Forte	AV	MP NP	C10442 C10444	P10442	10	0	20
						PDP	C10442 C10446	P10442	10	0	20
			а	APO-Paracetamol/ Codeine 500/30	ТΧ	MP NP	C10442 C10444	P10444	20	0	20
						PDP	C10442 C10446	P10446	20	0	20
			а	Codalgin Forte	AF	MP NP	C10442 C10444	P10444	20	0	20
						PDP	C10442 C10446	P10446	20	0	20
			а	Codapane Forte 500/30	AL	MP NP	C10442 C10444	P10444	20	0	20
				000100		PDP	C10442 C10446	P10446	20	0	20
			а	Comfarol Forte	SZ	MP NP	C10442 C10444	P10444	20	0	20
						PDP	C10442 C10446	P10446	20	0	20
			а	Panadeine Forte	SW	MP NP	C10442 C10444	P10444	20	0	20
						PDP	C10442 C10446	P10446	20	0	20

а	Paracetamol/Codei ne GH 500/30	GQ	MP NP	C10442 C10444	P10444	20	0	20
	ne GH 500/50		PDP	C10442 C10446	P10446	20	0	20
а	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

erric de	erisomaltose	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]		e 1, entry for Fluoxetine in th ert in the columns in the order ind	-	• • •		-	aded "Brand":			
			a	BTC Fluoxetine	JB	MP NP	C4755 C6277	28	5	28
	<b>(b)</b> <i>ins</i>	ert in the columns in the order ind	licated, and in c	lphabetical order	for the c	column hea	nded "Brand":			
			a	Fluoxetine APC	TEX TY	MP NP	C4755 C6277	28	5	28
[39]		e 1, entry for Golimumab in t	-	-		-		um Quantity:	1; Numl	per of Repeats: 3]
		it from the column headed "Circu						240404		
	( )	ert in numerical order in the colu it from the column headed "Purpe			0434 C	10435 C1	0436 C10461 C10490 0	510491		
		it from the column headed "Purn		/X//X PX//Y						
	.,	<i>i</i> 1			D10420	C D10100	D10404			
	( <b>d</b> ) ins	ert in numerical order in the colu	mn headed "Pu	rposes": <b>P10435</b>				0	4 N	
[40]	(d) ins Schedule	ert in numerical order in the colu e 1, entry for Golimumab in t	mn headed "Pu he form Injec	<i>rposes":</i> P10435 tion 50 mg in 0.	5 mL si	ingle use	pre-filled pen [Maxim	um Quantity:	1; Numl	per of Repeats: 5]
[40]	(d) ins Schedule (a) om	ert in numerical order in the colu e 1, entry for Golimumab in t it from the column headed "Circu	mn headed "Pu he form Injec umstances": C8	rposes": P10435 tion 50 mg in 0. 155 C8201 C822	5 mL si 23 C822	ingle use 24 C8225	pre-filled pen <i>[Maxim</i> C8229	-	1; Numt	per of Repeats: 5]
[40]	(d) ins Schedule (a) om (b) ins	ert in numerical order in the colu e 1, entry for Golimumab in t it from the column headed "Circu ert in numerical order in the colum	mn headed "Pu he form Injec umstances": C8 mn headed "Ciu	rposes": P10435 tion 50 mg in 0. 155 C8201 C822 rcumstances": C1	5 mL si 23 C822	ingle use 24 C8225	pre-filled pen <i>[Maxim</i> C8229	-	1; Numt	per of Repeats: 5]
[40]	<ul> <li>(d) ins</li> <li>Schedule</li> <li>(a) om</li> <li>(b) ins</li> <li>(c) om</li> </ul>	ert in numerical order in the colu e 1, entry for Golimumab in t it from the column headed "Circu ert in numerical order in the colu it from the column headed "Purpo	mn headed "Pu he form Injec umstances": C8 mn headed "Cin oses": P8155 F	rposes": P10435 tion 50 mg in 0. 155 C8201 C822 rcumstances": C1 P8224 P8225	5 mL si 23 C822 0434 C	ingle use 24 C8225 10435 C1	pre-filled pen <i>[Maxim</i> C8229	-	1; Numl	per of Repeats: 5]
	<ul> <li>(d) ins</li> <li>Schedule</li> <li>(a) om</li> <li>(b) ins</li> <li>(c) om</li> <li>(d) ins</li> <li>Schedule</li> </ul>	ert in numerical order in the colu e 1, entry for Golimumab in t it from the column headed "Circu ert in numerical order in the colu it from the column headed "Purpo ert in numerical order in the colu e 1, entry for Golimumab in t	mn headed "Pu he form Injec umstances": C8 mn headed "Cin oses": P8155 F mn headed "Pu	rposes": P10435 tion 50 mg in 0. 155 C8201 C822 ccumstances": C1 P8224 P8225 rposes": P10434	5 mL si 23 C822 0434 C P1046′	ingle use 24 C8225 10435 C1 1	pre-filled pen <i>[Maxim</i> C8229 0436 C10461 C10490 (	C10491		per of Repeats: 5]
	<ul> <li>(d) ins</li> <li>Schedule</li> <li>(a) om</li> <li>(b) ins</li> <li>(c) om</li> <li>(d) ins</li> <li>Schedule</li> <li>Number</li> </ul>	ert in numerical order in the colu e 1, entry for Golimumab in t it from the column headed "Circu ert in numerical order in the colum it from the column headed "Purpe ert in numerical order in the colum e 1, entry for Golimumab in t of Repeats: 3]	mn headed "Pu he form Injec umstances": C8 mn headed "Cir oses": P8155 F mn headed "Pu he form Injec	rposes ": P10435 tion 50 mg in 0. 155 C8201 C822 coumstances ": C1 P8224 P8225 rposes ": P10434 tion 50 mg in 0.	5 mL si 23 C822 0434 C P1046 <sup>4</sup> 5 mL si	ingle use 24 C8225 10435 C1 1 ingle use	pre-filled pen <i>[Maxim</i> C8229 0436 C10461 C10490 ( pre-filled syringe <i>[Ma</i>	C10491		per of Repeats: 5]
	<ul> <li>(d) ins</li> <li>Schedule</li> <li>(a) om</li> <li>(b) ins</li> <li>(c) om</li> <li>(d) ins</li> <li>Schedule</li> <li>Number</li> <li>(a) om</li> </ul>	ert in numerical order in the colu e 1, entry for Golimumab in t it from the column headed "Circu ert in numerical order in the colu it from the column headed "Purpo ert in numerical order in the colu e 1, entry for Golimumab in t	mn headed "Pu he form Injec umstances": C8 mn headed "Cin oses": P8155 F mn headed "Pu he form Injec umstances": C8	rposes ": P10435 tion 50 mg in 0. 155 C8201 C822 ccumstances ": C1 P8224 P8225 rposes ": P10434 tion 50 mg in 0.	5 mL si 23 C822 0434 C P1046 <sup>-</sup> 5 mL si 23 C822	ingle use 24 C8225 10435 C1 1 ingle use 24 C8225	pre-filled pen <i>[Maxim</i> C8229 0436 C10461 C10490 ( pre-filled syringe <i>[Ma</i> C8229	C10491 ximum Quant		per of Repeats: 5]
[40] [41]	<ul> <li>(d) ins</li> <li>Schedule</li> <li>(a) om</li> <li>(b) ins</li> <li>(c) om</li> <li>(d) ins</li> <li>Schedule</li> <li>Number</li> <li>(a) om</li> <li>(b) ins</li> </ul>	ert in numerical order in the colument end for the column headed "Circuster it from the column headed "Circuster ert in numerical order in the column it from the column headed "Purpo- ert in numerical order in the colument end for the column headed in the of Repeats: 3] it from the column headed "Circuster	mn headed "Pu he form Injec umstances": C8 mn headed "Cir oses": P8155 F mn headed "Pu he form Injec umstances": C8 mn headed "Cir	rposes ": P10435 tion 50 mg in 0. 155 C8201 C822 coumstances ": C1 P8224 P8225 rposes ": P10434 tion 50 mg in 0. 155 C8201 C822	5 mL si 23 C822 0434 C P1046 <sup>-</sup> 5 mL si 23 C822	ingle use 24 C8225 10435 C1 1 ingle use 24 C8225	pre-filled pen <i>[Maxim</i> C8229 0436 C10461 C10490 ( pre-filled syringe <i>[Ma</i> C8229	C10491 ximum Quant		per of Repeats: 5]
	<ul> <li>(d) ins</li> <li>Schedule</li> <li>(a) om</li> <li>(b) ins</li> <li>(c) om</li> <li>(d) ins</li> <li>Schedule</li> <li>Number</li> <li>(a) om</li> <li>(b) ins</li> <li>(c) om</li> </ul>	ert in numerical order in the colument end for the column headed "Circustion ert in numerical order in the column it from the column headed "Purpo- ert in numerical order in the column end for the column headed "Purpo- ert in numerical order in the column of Repeats: 3] it from the column headed "Circustion ert in numerical order in the column	mn headed "Pu he form Injec umstances": C8 mn headed "Cir oses": P8155 F mn headed "Pu he form Injec umstances": C8 mn headed "Cir oses": P8201 F	rposes ": P10435 tion 50 mg in 0. 155 C8201 C822 roumstances ": C1 P8224 P8225 rposes ": P10434 tion 50 mg in 0. 155 C8201 C822 roumstances ": C1 P8223 P8229	5 mL si 23 C822 0434 C P1046 <sup>7</sup> 5 mL si 23 C822 0434 C	ingle use 24 C8225 10435 C1 1 ingle use 24 C8225 10435 C1	pre-filled pen <i>[Maxim</i> C8229 0436 C10461 C10490 ( pre-filled syringe <i>[Ma</i> C8229 0436 C10461 C10490 (	C10491 ximum Quant		per of Repeats: 5]
	<ul> <li>(d) ins</li> <li>Schedule</li> <li>(a) om</li> <li>(b) ins</li> <li>(c) om</li> <li>(d) ins</li> <li>Schedule</li> <li>Number</li> <li>(a) om</li> <li>(b) ins</li> <li>(c) om</li> <li>(d) ins</li> <li>Schedule</li> </ul>	ert in numerical order in the colument e 1, entry for Golimumab in t it from the column headed "Circu ert in numerical order in the colum it from the column headed "Purper ert in numerical order in the colument of Repeats: 3] it from the column headed "Circu ert in numerical order in the colument it from the column headed "Purper	mn headed "Pu he form Injec umstances": C8 mn headed "Cir oses": P8155 F mn headed "Pu he form Injec umstances": C8 mn headed "Cir oses": P8201 F mn headed "Pu	rposes ": P10435 tion 50 mg in 0. 155 C8201 C822 coumstances ": C1 P8224 P8225 rposes ": P10434 tion 50 mg in 0. 155 C8201 C822 coumstances ": C1 P8223 P8229 rposes ": P10435	5 mL si 23 C822 0434 C P1046 <sup>7</sup> 5 mL si 23 C822 0434 C P10430	ingle use 24 C8225 10435 C1 1 ingle use 24 C8225 10435 C1 6 P10490	pre-filled pen <i>[Maxim</i> C8229 0436 C10461 C10490 ( pre-filled syringe <i>[Ma</i> C8229 0436 C10461 C10490 ( P10491	C10491 ximum Quant C10491	ity: 1;	per of Repeats: 5]
[41]	<ul> <li>(d) ins</li> <li>Schedule</li> <li>(a) om</li> <li>(b) ins</li> <li>(c) om</li> <li>(d) ins</li> <li>Schedule</li> <li>Number</li> <li>(a) om</li> <li>(b) ins</li> <li>(c) om</li> <li>(d) ins</li> <li>Schedule</li> <li>Number</li> </ul>	ert in numerical order in the colument end in numerical order in the colument it from the column headed "Circu- ert in numerical order in the colument it from the column headed "Purper- ert in numerical order in the colument of Repeats: 3] it from the column headed "Circu- ert in numerical order in the colument it from the column headed "Purper- ert in numerical order in the colument it from the column headed "Purper- ert in numerical order in the colument ert in numerical order in the colument	mn headed "Pu he form Injec umstances": C8 mn headed "Cin oses": P8155 F mn headed "Pu he form Injec umstances": C8 mn headed "Cin oses": P8201 F mn headed "Pu he form Injec	rposes ": P10435 tion 50 mg in 0. 155 C8201 C822 recumstances ": C1 P8224 P8225 rposes ": P10434 tion 50 mg in 0. 155 C8201 C822 recumstances ": C1 P8223 P8229 rposes ": P10435 tion 50 mg in 0.	5 mL si 23 C822 0434 C P1046 5 mL si 23 C822 0434 C P10430 5 mL si	ingle use 24 C8225 10435 C1 1 ingle use 24 C8225 10435 C1 6 P10490 ingle use	pre-filled pen <i>[Maxim</i> C8229 0436 C10461 C10490 ( pre-filled syringe <i>[Ma</i> C8229 0436 C10461 C10490 ( P10491 pre-filled syringe <i>[Ma</i>	C10491 ximum Quant C10491	ity: 1;	per of Repeats: 5]

(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	Injection	а	Dilaudid	MF	MP NP	C10439		5	0	5
	2 mg in 1 mL		а	HYDROMORPHON E JUNO	JU	MP NP	C10439		5	0	5
			а	MEDSURGE HYDROMORPHON E 2 mg/1 mL		MP NP	C10439		5	0	5
	Injection containing hydromorphone hydrochloride	Injection	а	Dilaudid-HP	MF	MP NP	C10439		5	0	5
	10 mg in 1 mL		а	HYDROMORPHON E JUNO-HP	JU	MP NP	C10439		5	0	5
			а	MEDSURGE HYDROMORPHON E HP 10 mg/1 mL		MP NP	C10439		5	0	5
	Oral liquid containing	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
	nydrochionde z mg					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	Oral		Dilaudid	MF	MP NP	C10439 C10451	P10451	10	0	20
	hydrochloride 4 mg					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	e Oral	Dilaudid	MF	MP NP	C10439 C10451	P10451	10	0	20
nyurochionue o mg				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	Se 3	e Note	e See Note 3	14	D(100)
46]	Schedule 1, entry for Levodopa with carbidopa omit:										
	Tablet (modified release) 200 mg- Oral 50 mg	Carbidopa and Levodopa Extended-release Tablets	DZ	MP NP	C5253		10	0	5	100	
47]	Schedule 1, entry for Mepolizumab insert as first entry:										
	Injection 100 mg in 1 mL single Injection dose pre-filled pen	Nucala	GK	MP	See Note 3	See Note 3	Se 3	e Note	e See Note 3	1	D(100)

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

#### omit:

		а	Metformin generichealth 1000	GQ	MP NP		90	5	90
[49]	Schedule 1, entry for Methadone in omit from the column headed "Circumsta	-	ion containing me substitute: C104		one hydr	ochloride 10 mg in 1 mL			
[50]	Schedule 1, entry for Methadone in omit from the column headed "Circumsta		t containing metha substitute: C104		e hydroc	hloride 10 mg			
[51]	Schedule 1, entry for Montelukast in insert in the columns in the order indicate		· · •		•				
		а	Montelukast Lupin	HQ	MP NP	C6666	28	5	28
[52]	Schedule 1, entry for Montelukast in insert in the columns in the order indicate								
		а	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	Injection		Morphine Juno	JU	MP NP MW	C10472	5	0	5
hydrochloride trihydrate 10 mg in 1 mL					PDP	C10478	5	0	5
Injection containing morphine	Injection		Hospira Pty Limited	PF	MP NP MW	C10472	5	0	5
sulfate pentahydrate 10 mg in 1 mL					PDP	C10478	5	0	5
			MORPHINE	DZ	MP NP MW	C10472	5	0	5
			SULFATE 10 mg/1 mL MEDSURGE		PDP	C10478	5	0	5
Injection containing morphine	Injection	а	Hospira Pty Limited	PF	MP NP MW	C10472	5	0	5
sulfate pentahydrate 15 mg in 1 mL					PDP	C10478	5	0	5
		а	MORPHINE	DZ	MP NP MW	C10472	5	0	5
			SULFATE 15 mg/1 mL MEDSURGE		PDP	C10478	5	0	5
Injection containing morphine	Injection		Morphine Juno	JU	MP NP	C10472	5	0	5
hydrochloride trihydrate 20 mg in 1 mL					PDP	C10478	5	0	5
Injection containing morphine	Injection	а	Hospira Pty Limited	PF	MP NP	C10472	5	0	5
sulfate pentahydrate 30 mg in 1 mL					PDP	C10478	5	0	5
		а	MORPHINE	DZ	MP NP	C10472	5	0	5
			SULFATE 30 mg/1 mL MEDSURGE		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 Junc	JU	MP NP	C10472	5	0	5	
	Oral solution containing morphine hydrochloride trihydrate 2 mg per	Oral	Ordine 2	MF	MP NP	C10439	1	0	1	
	mL, 200 mL				PDP	C10440	1	0	1	
	Oral solution containing morphine hydrochloride trihydrate 5 mg per	Oral	Ordine 5	MF	MP NP	C10439	1	0	1	
	mL, 200 mL				PDP	C10440	1	0	1	
	Oral solution containing morphine hydrochloride trihydrate 10 mg	Oral	Ordine 10	MF	MP NP	C10439	1	0	1	
	per mL, 200 mL				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		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		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		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 10		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 20		MP NP	C10466 C10487	28	0	28	
	Tablet containing morphine sulfate pentahydrate 5 mg	Oral	MS Contin	MF	MP NP	C10445	28	0	28	
Instrument Number Pi			16							

[											
	(controlled release)										
	Tablet containing morphine sulfate pentahydrate 10 mg	Oral		Sevredol	MF	MP NP	C6168 C10486	P10486	20	0	20
	surface perturby arace to mg					MP NP	C6168 C10486	P6168	20	2	20
	Tablet containing morphine sulfate pentahydrate 10 mg	Oral	а	Momex SR 10	RW	MP NP	C10445		28	0	28
	(controlled release)		а	Morphine MR AN	EA	MP NP	C10445		28	0	28
			а	MORPHINE MR APOTEX	ТΧ	MP NP	C10445		28	0	28
			а	Morphine MR Mylan	AF	MP NP	C10445		28	0	28
			а	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	Oral		Sevredol	MF	MP NP	C6168 C10486	P10486	20	0	20
	sulfate pentahydrate 20 mg					MP NP	C6168 C10486	P6168	20	2	20
	Tablet containing morphine	Oral		Anamorph	RW	MP NP	C10439 C10451	P10451	10	0	20
	sulfate pentahydrate 30 mg					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	Oral	а	Momex SR 30	RW	MP NP	C10445		28	0	28
	sulfate pentahydrate 30 mg (controlled release)		а	Morphine MR AN	EA	MP NP	C10445		28	0	28
			а	MORPHINE MR APOTEX	тх	MP NP	C10445		28	0	28
			а	Morphine MR Mylan	AF	MP NP	C10445		28	0	28
			а	MS Contin	MF	MP NP	C10445		28	0	28
	Tablet containing morphine	Oral	а	Momex SR 60	RW	MP NP	C10445		28	0	28
	sulfate pentahydrate 60 mg (controlled release)		а	Morphine MR AN	EA	MP NP	C10445		28	0	28
			а	MORPHINE MR APOTEX	ТΧ	MP NP	C10445		28	0	28

				а	Morphine MR Mylan	AF	MP NP	C10445		28	0	28
				а	MS Contin	MF	MP NP	C10445		28	0	28
		Tablet containing morphine	Oral	а	Momex SR 100	RW	MP NP	C10445		28	0	28
		sulfate pentahydrate 100 mg (controlled release)		а	Morphine MR AN	EA	MP NP	C10445		28	0	28
				а	MORPHINE MR APOTEX	ТΧ	MP NP	C10445		28	0	28
				а	Morphine MR Mylan	AF	MP NP	C10445		28	0	28
				а	MS Contin	MF	MP NP	C10445		28	0	28
		Tablet containing morphine sulfate pentahydrate 200 mg	Oral		MS Contin	MF	MP NP	C6151 C10466 C10487	P10466 P10487	28	0	28
		(controlled release)					MP NP	C6151 C10466 C10487	P6151	28	2	28
[54]	Schedule 1	I, entry for Oxycodone										
	substitute:											
Oxycodon	e	Capsule containing oxycodone hydrochloride 5 mg	Oral	а	Oxycodone BNM	LI	MP NP	C10442 C10444	P10442	10	0	20
		nydrochionde 5 mg					PDP	C10442 C10446	P10442	10	0	20
				а	OxyNorm	MF	MP NP	C10442 C10444	P10442	10	0	20
							PDP	C10442 C10446	P10442	10	0	20
				а	Oxycodone BNM	LI	MP NP	C10442 C10444	P10444	20	0	20
							PDP	C10442 C10446	P10446	20	0	20
				а	OxyNorm	MF	MP NP	C10442 C10444	P10444	20	0	20
							PDP	C10442 C10446	P10446	20	0	20
		Capsule containing oxycodone	Oral	а	Oxycodone BNM	LI	MP NP	C10442 C10444	P10442	10	0	20
		hydrochloride 10 mg					PDP	C10442 C10446	P10442	10	0	20
				а	OxyNorm	MF	MP NP	C10442 C10444	P10442	10	0	20
				а	OxyNorm	MF	mp np PDp	C10442 C10444 C10442 C10446		10 10	0 0	20 20

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

Tablet containing oxycodone	Oral	а	Novacodone	ΗX	MP NP	C10445	28	0	28
hydrochloride 20 mg (controlled release)		а	Oxycodone Sandoz	SZ	MP NP	C10445	28	0	28
		а	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	Oral	а	Novacodone	HX	MP NP	C10445	28	0	28
hydrochloride 40 mg (controlled release)		а	Oxycodone Sandoz	SZ	MP NP	C10445	28	0	28
		а	OxyContin	MF	MP NP	C10445	28	0	28
Tablet containing oxycodone	Oral	а	Novacodone	ΗХ	MP NP	C10445	28	0	28
hydrochloride 80 mg (controlled release)		а	Oxycodone Sandoz	SZ	MP NP	C10445	28	0	28
		а	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 naloxone hydrochloride 20 mg	the form Tablet (	contr	olled release) containing ox	ycodone hydrocl	nloride	40 mg with	
	omit from the column headed "Circumstances": C4951	substitute: C10	445					
[62]	Schedule 1, entry for Oxycodone with naloxone in naloxone hydrochloride 30 mg	the form Tablet (	contr	olled release) containing ox	ycodone hydrocl	nloride	60 mg with	
	omit from the column headed "Circumstances": C4951	substitute: C10	445					
[63]	Schedule 1, entry for Oxycodone with naloxone in naloxone hydrochloride 40 mg	the form Tablet (	contr	olled release) containing ox	ycodone hydrocl	nloride	80 mg with	
	omit from the column headed "Circumstances": C4951	substitute: C10	445					
[64]	Schedule 1, omit entry for Oxytocin							
[65]	Schedule 1, entry for Perindopril in the form Table	t containing peri	ndopi	ril erbumine 2 mg				
	(a) insert in the columns in the order indicated, and in a	lphabetical order fo	or the o	column headed "Brand":				
		BTC Perindopril	JB	MP NP	30	5	30	
	(b) insert in the columns in the order indicated, and in a	lphabetical order fo	or the d	column headed "Brand":				
		Perindopril APOTEX	ΤY	MP NP	30	5	30	
[66]	Schedule 1, entry for Perindopril in the form Table	t containing peri	ndop	ril erbumine 4 mg				
	(a) insert in the columns in the order indicated, and in a	lphabetical order fo	or the d	column headed "Brand":				
		BTC Perindopril	JB	MP NP	30	5	30	
	(b) insert in the columns in the order indicated, and in a	lphabetical order fo	or the d	column headed "Brand":				
		Perindopril APOTEX	ΤY	MP NP	30	5	30	
[67]	Schedule 1, entry for Perindopril in the form Table	t containing peri	ndopi	ril erbumine 8 mg				
	(a) insert in the columns in the order indicated, and in a	lphabetical order fo	or the d	column headed "Brand":				
		BTC Perindopril	JB	MP NP	30	5	30	
L	(b) insert in the columns in the order indicated, and in a	lphabetical order fo	or the d	column headed "Brand":				
		Perindopril APOTEX	ΤY	MP NP	30	5	30	

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

omit:

	omit:												
		Oral liquid 500 mL, 8 (Nutrini Peptisorb Energy)	Oral		Nutrini Peptisorb Energy	NU	MP NP	C6890		10	5	1	
[69]	Schedule 1 substitute:	l, entry for Risperidone in	the form (	Oral so	olution 1 mg per	mL,	100 mL						
		Oral solution 1 mg per mL, 100 mL	Oral	а	Risperdal	JC	MP NP	C4246 C5907 C6898 C6899 C10020 C10021 C10052	P6898 P6899 P10020 P10021 P10052	1	2	1	
				а	Rixadone	AF	MP NP	C4246 C5907 C6898 C6899 C10020 C10021 C10052	P6898 P6899 P10020 P10021 P10052	1	2	1	
				а	Risperdal	JC	MP NP	C4246 C5907 C6898 C6899 C10020 C10021 C10052	P4246 P5907	1	5	1	
				а	Rixadone	AF	MP NP	C4246 C5907 C6898 C6899 C10020 C10021 C10052	P4246 P5907	1	5	1	
[70]	Schedule 1 substitute:	, entry for Sevelamer											
Sevelamer		Tablet containing sevelamer	Oral		Sevelamer Apotex	ТΧ	MP NP	C5491		180	5	180	
		carbonate 800 mg			Sevelamer Lupin	GQ	MP NP	C5491		180	5	180	
					Sevelamer Apotex	ТΧ	MP	C5530 C9762		360	5	180	C(100)
					Sevelamer Lupin	GQ	MP	C5530 C9762		360	5	180	C(100)
		Tablet containing sevelamer	Oral		Renagel	GZ	MP NP	C5491		180	5	180	
		hydrochloride 800 mg					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*:

				а	Terbinafine GH	GQ	MP NP	C6395 C6404 C6453	P6404 P6453	42	0	42
	<b>(b)</b> <i>omit:</i>											
				а	Terbinafine GH	GQ	MP NP	C6395 C6404 C6453	P6395	42	1	42
75]	Schedule 1	1, entry for Tramadol										
	substitute:											
ramadol		Capsule containing tramadol	Oral	а	APO-Tramadol	ТΧ	MP NP	C10442 C10444	P10442	10	0	20
		hydrochloride 50 mg					PDP	C10442 C10446	P10442	10	0	20
				а	Chem mart Tramadol	СН	MP NP	C10442 C10444	P10442	10	0	20
					Tramador		PDP	C10442 C10446	P10442	10	0	20
				а	Terry White Chemists Tramadol	ΤW	MP NP	C10442 C10444	P10442	10	0	20
					Chemists Tramador		PDP	C10442 C10446	P10442	10	0	20
				а	Tramadol AMNEAL	EF	MP NP	C10442 C10444	P10442	10	0	20
							PDP	C10442 C10446	P10442	10	0	20
				а	Tramadol AN	EA	MP NP	C10442 C10444	P10442	10	0	20
							PDP	C10442 C10446	P10442	10	0	20
				а	Tramadol Sandoz	SZ	MP NP	C10442 C10444	P10442	10	0	20
							PDP	C10442 C10446	P10442	10	0	20
				а	Tramadol SCP	CR	MP NP	C10442 C10444	P10442	10	0	20
							PDP	C10442 C10446	P10442	10	0	20

	а	Tramal	CS	MP NP	C10442 C10444	P10442	10	0	20
				PDP	C10442 C10446	P10442	10	0	20
	а	Tramedo	AF	MP NP	C10442 C10444	P10442	10	0	20
				PDP	C10442 C10446	P10442	10	0	20
	а	Zydol	RW	MP NP	C10442 C10444	P10442	10	0	20
				PDP	C10442 C10446	P10442	10	0	20
	а	APO-Tramadol	тх	MP NP	C10442 C10444	P10444	20	0	20
				PDP	C10442 C10446	P10446	20	0	20
	а	Chem mart	СН	MP NP	C10442 C10444	P10444	20	0	20
		Tramadol		PDP	C10442 C10446	P10446	20	0	20
	а	Terry White	TW	MP NP	C10442 C10444	P10444	20	0	20
		Chemists Tramadol		PDP	C10442 C10446	P10446	20	0	20
	а	Tramadol AMNEAL	EF	MP NP	C10442 C10444	P10444	20	0	20
				PDP	C10442 C10446	P10446	20	0	20
	а	Tramadol AN	EA	MP NP	C10442 C10444	P10444	20	0	20
				PDP	C10442 C10446	P10446	20	0	20
	а	Tramadol Sandoz	SZ	MP NP	C10442 C10444	P10444	20	0	20
				PDP	C10442 C10446	P10446	20	0	20
	а	Tramadol SCP	CR	MP NP	C10442 C10444	P10444	20	0	20
				PDP	C10442 C10446	P10446	20	0	20
	а	Tramal	cs	MP NP	C10442 C10444	P10444	20	0	20
				PDP	C10442 C10446	P10446	20	0	20
	а	Tramedo	AF	MP NP	C10442 C10444	P10444	20	0	20
				PDP	C10442 C10446	P10446	20	0	20
	а	Zydol	RW	MP NP	C10442 C10444	P10444	20	0	20
				PDP	C10442 C10446	P10446	20	0	20
12 of 2020		24							

	Injection containing tramadol hydrochloride 100 mg in 2 mL	Injection	а	Tramadol ACT	JO	MP NP	C10444	5	0	5
						PDP	C10446	5	0	5
			а	Tramadol AN	JU	MP NP	C10444	5	0	5
						PDP	C10446	5	0	5
			а	Tramadol Sandoz	SZ	MP NP	C10444	5	0	5
						PDP	C10446	5	0	5
			а	Tramal 100	CS	MP NP	C10444	5	0	5
						PDP	C10446	5	0	5
	Oral drops containing tramadol hydrochloride 100 mg per mL, 10	Oral		Tramal	CS	MP NP	C10444	1	0	1
	mL					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	Oral	а	APO-Tramadol SR	ТΧ	MP NP	C10445	20	0	20
	100 mg		а	Chem mart Tramadol SR	СН	MP NP	C10445	20	0	20
			а	Terry White Chemists Tramadol SR	τw	MP NP	C10445	20	0	20
			а	Tramadol AN SR	EA	MP NP	C10445	20	0	20
			а	Tramadol Sandoz SR	SZ	MP NP	C10445	20	0	20
			а	Tramadol SR generichealth	GQ	MP NP	C10445	20	0	20
			а	Tramal SR 100	CS	MP NP	C10445	20	0	20
			а	Tramedo SR	AL	MP NP	C10445	20	0	20
			а	Zydol SR 100	RW	MP NP	C10445	20	0	20
	Tablet (sustained release) containing tramadol hydrochloride	Oral	а	APO-Tramadol SR	ТΧ	MP NP	C10445	20	0	20
	150 mg		а	Chem mart Tramadol SR	СН	MP NP	C10445	20	0	20
Instrument Number Pl	B 42 of 2020			25						

		а	Terry White Chemists Tramadol SR	TW	MP NP	C10445	20	0	20
		а	Tramadol AN SR	EA	MP NP	C10445	20	0	20
		а	Tramadol Sandoz SR	SZ	MP NP	C10445	20	0	20
		а	Tramadol SR generichealth	GQ	MP NP	C10445	20	0	20
		а	Tramal SR 150	CS	MP NP	C10445	20	0	20
		а	Tramedo SR	AL	MP NP	C10445	20	0	20
		а	Zydol SR 150	RW	MP NP	C10445	20	0	20
	Tablet (sustained release) Oral containing tramadol hydrochloride	а	APO-Tramadol SR	ТΧ	MP NP	C10445	20	0	20
	200 mg	а	Chem mart Tramadol SR	СН	MP NP	C10445	20	0	20
		а	Terry White Chemists Tramadol SR	τw	MP NP	C10445	20	0	20
		а	Tramadol AN SR	EA	MP NP	C10445	20	0	20
		а	Tramadol Sandoz SR	SZ	MP NP	C10445	20	0	20
		а	Tramadol SR generichealth	GQ	MP NP	C10445	20	0	20
		а	Tramal SR 200	CS	MP NP	C10445	20	0	20
		а	Tramedo SR	AL	MP NP	C10445	20	0	20
		а	Zydol SR 200	RW	MP NP	C10445	20	0	20
[76]	Schedule 1, entry for Valsartan with hydrochloro	othia	zide in the form	Tabl	et 80 mg-1	2.5 mg			
	(a) insert in the column headed "Schedule Equivalent	t" for	the existing brand	"Co-	Diovan 80/1	2.5": <b>a</b>			
	(b) insert in the columns in the order indicated, and in	n alpk	habetical order for	the c	olumn heade	d "Brand":			
		а	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":

	- <b>,</b>				a	Dilart HCT 160/12.5	5 AF	MP NP	C4374	28	5	28	
[78] S	chedul	e 1, entr	y for Va	alsartan	with hydrochlorothia	azide in the form	Table	et 160 m	g-25 mg				
			-		'Schedule Equivalent" fo								
(t	b) ins	ert in the	columns	s in the of	rder indicated, and in alp	phabetical order for	the co	olumn hea	ded "Brand":				
					а	Dilart HCT 160/25	AF	MP NP	C4374	28	5	28	
[79] S	chedul	e 1, entr	y for Va	alsartan	with hydrochlorothia	azide in the form	Table	et 320 m	g-12.5 mg				
(a	a) ins	ert in the	column	headed '	'Schedule Equivalent" fo	or the existing brand	"Со-	Diovan 3	20/12.5": <b>a</b>				
(k	<b>b)</b> ins	ert in the	columns	s in the of	rder indicated, and in alp	phabetical order for	the co	olumn hea	ded "Brand":				
					а	Dilart HCT 320/12.5	5 AF	MP NP	C4361	28	5	28	
a)	a) ins	ert in the	column	headed '	with hydrochlorothia 'Schedule Equivalent" fo rder indicated, and in alp	or the existing brand	"Со-	Diovan 3.	20/25": <b>a</b>				
					а	Dilart HCT 320/25	AF	MP NP	C4361	28	5	28	
	schedule	e 4, Part	: 1, afte	r entry f	or Amino acid formu	la with carbohyd	rate,	vitamins	, minerals and t	race elements wit	hout p	henylalan	ine
Amino acid for with carbohyd without pheny	frate	C4295			Phenylketonuria								
	Schedule	e 4, Part	1, afte	r entry f	or Amino acid formu	la with fat, carbo	hydra	ate, vitar	nins, minerals, f	race elements an	d medi	um chain	triglycerides
Amino acid for with fat, carbo without methic	ohydrate	C5534			Pyridoxine non-responsive	homocystinuria							
	schedule	e 4, Part	1, afte	r entry f	or Amino acid formu	la with fat, carbo	hydra	ate with	out phenylalanin	e			
Amino acid for	ormula	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] Schedul (a) om		ry for Bortezomib	
	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) om	it:		
	C7984	Symptomatic multiple myeloma Initial PBS-subsidised treatment Patient must be newly diagnosed; AND Patient must have severe acute renal failure; AND Patient must have severe acute renal failure; AND Patient must have severe acute renal failure; AND 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 yltic 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 (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) inse	ert in numerical order afte	r existing text:	
		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 Patient 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 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-s	Compliance with Authority Required procedures - Streamlined Authority Code 10426
		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
(		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	4 P10464	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).	Compliance with Authority Required procedures - Streamlined Authority Code 10464
C10482	2 P10482	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.	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	Compliance with
		The condition must require daily, continuous, long term therapy with this treatment; AND	Authority Required
		Patient must have pain directly attributable to cancer; OR	procedures -
		Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non- opioid or other opioid analgesics; OR	Streamlined Authority Code 10445
		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.	
	1		1

				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:

	1		
C10431	P10431	<ul> <li>Non-radiographic axial spondyloarthritis</li> <li>Continuing treatment</li> <li>Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; AND</li> <li>Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND</li> <li>The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.</li> <li>Must be treated by a rheumatologist; OR</li> <li>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</li> <li>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:</li> <li>(a) a CRP measurement no greater than 10 mg per L; or</li> <li>(b) a CRP measurement reduced by at least 20% from baseline.</li> <li>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.</li> <li>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.</li> </ul>	Compliance with Written Authority Required procedures
C10456	P10456	<ul> <li>Non-radiographic axial spondyloarthritis</li> <li>Initial treatment - Initial 2 (Change or re-commencement of treatment after a break in biological medicine of less than 5 years)</li> <li>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; AND</li> <li>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</li> <li>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</li> <li>Patient must not neceive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction.</li> <li>Patient must be aged 18 years or older.</li> <li>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</li> <li>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.</li> <li>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.</li> <li>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:</li> <li>(a) a CRP measurement neduced by at least 20% from baseline.</li> <li>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.</li> <li>BASDAI scores and CRP levels must be documented in the patient's medical records.</li> <li>The assessment of the patient's re</li></ul>	Compliance with Written Authority Required procedures

	<ul> <li>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:</li> <li>(a) a completed authority prescription form; and</li> <li>(b) a completed Non-radiographic axial spondyloarthritis change or recommencement of treatment PBS Authority Application - Supporting Information Form which seeks:</li> <li>(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</li> <li>(ii) confirmation that the patient has failed to achieve an adequate response with the most recent supply of biological medicine; or</li> <li>(iii) confirmation that an intolerance to the most recent supply of biological medicine had occurred; and</li> <li>(iv) an updated BASDAI score and CRP level if new baseline measurements are to be used for future assessments of response</li> </ul>	
C10458	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 been can expect and expense 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 sacrolilitis or Grade III or IV unilateral sacrolilitis 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 sacrolilitis 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 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	Compliance with Written Authority Required procedures

			<ul> <li>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.</li> <li>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.</li> <li>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 and no later than 4 weeks from the continuing treatment criteria.</li> <li>The authority application must be made in writing and must include:</li> <li>(a) a completed authority prescription form; and</li> <li>(b) a completed Non-radiographic axial spondyloarthritis Grandfathered PBS Authority Application - Supporting Information Form which seeks details of:</li> <li>(i) a copy of the radiological report confirming the absence of Grade II bilateral sacroilitis or Grade III or IV unilateral sacroilitis; and</li> <li>(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</li> <li>(iii) the MRI report; and</li> <li>(iv) the NSAIDs trialled, their doses and duration of treatment. If applicable, the reason a hi</li></ul>	
C1	10459	P10459	<ul> <li>Non-radiographic axial spondyloarthritis</li> <li>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</li> <li>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</li> <li>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</li> <li>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</li> <li>Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment; OR</li> <li>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</li> <li>The treatment must provide no more than the balance of up to 20 weeks treatment.</li> <li>Must be treated by a rheumatologist; OR</li> <li>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</li> </ul>	Compliance with Written Authority Required procedures
C1	10468	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

Intercontinue to form the top form of the second sport/optical mits, as defined to yossessifiet to visco second the Magnetic Resonance Imaging (MR); AND         The continue must are presence of Bone Marrow Ocdema (BMO) depicted as a hyperintense signal on a Short Tau Investion Resonance Imaging (MR); AND         The continue must be aged 19 years or older.         Differed continue must be aged 19 years or older.         Must be treated by a chincle Immunologist with experiments, depending on the decage regiment, under this restriction.         Patient must be aged 19 years or older.         Must be treated by a chincle Immunologist with experiments in the management of non-indiographic axial spondyloarthitis.         The sponder that and the immunologist with experiments and the decage regiment. Under this restriction.         Patient must be aged 19 years or older.         Must be treated by a chince Immunologist with experiments in the management of non-indiographic axial spondyloarthitis.         The sponder that and the immunologist with experiment Tox-approved Product Information, the application must indive the reason a higher deex cannot be used.         If the indiverse intervent with NSAID is indiverse in decayable response to NSAIDs and must be demonstrated at the time of the following in the indicate failure to achieve and adequate response to NSAIDs and must be demonstrated at the time of the following in the regiment in the spondiation of the indicate failure to achieve and adequate response to NSAIDs and must be demonstrated at the time of the following indicate CPR level cound in the time of india application.         If the contraint dintervent develops dur		1		The condition must be non-radiographic avial anondulgarthritic, as defined by Accomment of Chandulgarthritic International	
The condition must be sarcelities with active inflammation and/or operating an on non-contrast Magnetic Resonance Imaging (MR); AND           The condition must have presence of Bone Marrow Oedema (BMO) depided as hyperintense signal on a Short Tau Investigation Recovery (STR) image (or equivalent); AND The condition must have presence of Bone Marrow Oedema (BMO) applied as a hyperintense signal on a Short Tau Investigation Recovery (STR) image (or equivalent); AND The condition must not recover more than 18 to 20 weeks of treatment, depending on the desage regimen, under this restriction. Patient must to age of 19 years or older. Must be treated by a neumatologist OR Must be treated by a neumatologist of the NSAIDS traited, their doese and duration of treatment. If the NSAID does is the stat han the maximum accommended does in the relevant TGA-approved Product Information, the the statistic statistis statis statis statistic statistic statistic statistic statisti				The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria: AND	
Image: Simple set in the second sec				The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging	
Inversion Recovery (STIR) image (or equivalent); AND The condition must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Patient must be application must include details of the southorise in the management of non-radiographic axial spondyloarthritis. The application must include the reason and the source of the					
Patient must not receive more than 18 to 20 weeks of treatment, depending on the dosage regimen, under this restriction. Must be treated by a chical immunologist with repartise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAID statellet, their does and duration of treatment. If the NSAID does lises that the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAID statellet, their does and duration of treatment. If the NSAID does lises that the maximum recommended does in the relevant TGA-approved Product Information, the application must provide details of the contraindication unsurp rowth details of the contraindication details of the nature and severity of this indicarance. The following criteria indicate failure to achieve an adequate response to NSAID scale; and (b) C-reactive protein CRP) level greater than 10 mg pert. The tobacine CRP level greater than 10 mg pert. The tobacine contrained to a contrained to a second the perturbation of the same that the completion of the same that the topacitor must be stated in the application. The thereating the advection the same that the completion of the same that the same that stated in the application. The tobacine CRP level must be determined to an o the same that the same that stated in the application. The tobacine CRP level must be determined to a same the same that share that the topacine the same that the same that the				Inversion Recovery (STIR) image (or equivalent); AND	
Patient must be aged 18 years or older.         Must be treated by a memoralogist; OR         Must be treated by a memoralogist; OR         Must be treated by a memoralogist; OR         Must be treated by a divisition of the NSAD bis trialed, their doess and duration of treatment.         If the application must include the reason a higher does cannot be used.         If treatment with NSADS is contraindicated according to the relevant TGA-approved Product Information, the application must include the reason a higher does cannot be used.         If interame to NSAD treatment develops provide details of the nature and severity of this intolerance.         The following criteria indicate failure to achieve an adequate response to NSADs and must be demonstrated at the time of the initial application.         (a) a Bath Ankylosing Spondylius Disease Activity index (IASDA) 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 NSAD and exercise trial, but prior to ceasing NSADD treatment. All measures must be no more than 4 weeks for the reason must be stated in the application.         If the requirement and no late time and evelocid for the relevant TGA-approved Product Information, the application must be made in whiting and the evelocid on the met statement curves. If the response assessment is not constant and no late the relevant TGA application relevant CTGA application.         (c) C-reactive protein (CRP) level greater than 10 mg per L.       The baseline BASDM score; and (NASD treatm					
Must be treated by a chinacia munulogist: OR Must be treated by a chinacia munulogist of the NSAIDs trialed. their doses and duration of treatment. If the NSAID does is lass finant the maximum recommended does in the relevant TGA-approved Product Information, the application must include the reason a higher does cannot be used. If treatment with SAIDs is concommended does in the relevant TGA-approved Product Information, the application must include the reason a higher does cannot be used. If treatment with relevant TGA-approved Product Information, the application in the initial application. The following orients indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application. The following orients indicate failure to achieve an adequate response to NSAIDs and must be demonstrated at the time of the initial application. The baseline EASDAI score and CRP level must be determined the velopse and the gaptication. The baseline EASDAI score and CRP level must be determined that the completion of the application. If the requirement to demonstrate an elevated CRP level could not be must be addentified application. The baseline EASDAI score and CRP level must be determined that completion of the application. The baseline EASDAI score and CRP level must be determined to a collade the specification. The high contract on intravencous and policitation must include: (a) a completed on intravencous and end/yordenistone or equivalent just acceptable resson to intravencous and policitation must include: (a) a completed Abornation gram must include: (a) a completed Abornation gram must include: (a) a completed Abornation gram and include the application must be addentified that the application must he patient with the specification and policitation with specification with the specification and the application and the papplication is a secore of the application and th					
Must be treated by a clinical immunologit with expertise in the management of non-radiographic axial spondyloarthritis. The application must include de readials of the NSAID treatment. If the NSAID case is less than the maximum recommended does in the relevant TGA-approved Product Information, the application must include the reason a higher does cannot be used. If treatment with NSAID is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If inclinance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment with hybridsoin Spondyliny Index (RASDA) score and asswrity of this inclinance. The hoseine BASDAI score and CRPI level must be determined at the completion of the 3-month NSAID and exercise trial, but prot to ceasing NSAID treatment and Index Pole Period CRPI level quality (or equivalent) or a parenterial steriod within the pastication. The the sectime BASDAI score and CRPI level must network of treatment must be stated in the application. Treatment with predivisione doesd at 7.5 mg or higher daily (or equivalent) or a parenterial steriod within the pastication. The apseins the India course of Instement and the application acceptable reason. The apseins the India application and thy or development must be conducted following a minimum of 2 weeks of reatment and no later than 4 weeks for the control on targe true assessment is not conducted within these timeframes, the patient will be determined to have claiked this course. If the requirement cole The apseins BASDAI score and CRP level must necked (i) a completed Non-radiographic axial spondyloarthritis initial PBS Authority Application - Supporting Information Form which seeks details of the mathy eve					
The application must include details of the NSAIDs trailed, their does and duration of treatment.The application must include details of the NSAIDs trailed, their does and duration of treatment.If the NSAID is contraindicated according to the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.If reatment with NSAID is is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindicate according to the network of the sevenity of this infolerance.If integrance to NSAID statement develops during the relevant to AsAID statement and use to demonstrate at the time of the initial application.If intoerance to NSAID statement and must be demonstrated at the time of the initial application.If a Bath Ankylosing Scondyllis Disease Activity Index (IABSDAI) score of at least 4 on a 0-10 scale; and to if the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.If the metalize to achieve and CRP level could not be met, the reason must be stated in the application.If the requirement to the demonstrate an elevated CRP level could not be met, the reason must be stated in the application.If the requirement to the completed North repersenterial steroid within the gats month (intramuscular or intravenous methylopredinsione or equivalent) or a particular or intravenous methylopredinsione or equivalent (IABSDAI) secret and the relevant TGA-approved Product Information Form which seeks details of:If the mathematic application must be made in writing and must be demonstrate and level adult for programs.If a completed autority precision form; andIf a complete					
It the NSAD dose is less than the maximum recommende dose in the relevant TGA-approved Product Information, the application must include the reason a higher devant period of use which is of a severity to necessitate permanent treatment with NSAD is is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If infolderance to NSADD treatment develops during the relevant TGA-approved Product Information, the application must provide details of the nature and severity of this intolarence. The following criteria indicate failure to achieve an adequate response to NSADD s and must be demonstrated at the time of the initial application. (a) a Bath Ankylosing Spondylitis Disease Activity Index (IASDAD) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level great than 10 mg per L. The baseline BASDAI score and CRP level could not be met, the reason must be routed 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. If the requirement of demonstrate and levated CRP level could not be met, the reason must be stated in the application. If the requirement of the patient AI measures must be no more than 4 weeks to couldcate following a minimum of 12 weeks of treatment and no later than 4 weeks from the coaselon of that treatment streatment within the patient of the sponse assessment is not conducted within the set interfaces, the patient will be deemed to have treated at the streatment experiment of the patient and no later than 4 weeks atom the could at the time of the response assessment is not conducted within the set interface than unclude. If the response assessment is not conducted within the set interface the militial course of treatment and the relevant TGA-approved Product Information Form (Interament withe set addition or					
application must include the reason a higher dose cannot be used. If treatment with NSADE is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSADE 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 faulure to achieve an adequate response to NSADE treatment withdrawal, the application must provide details of the nature and severity of this intolerance. (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 NSAD and exercise trial, bit per to centrain (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 NSAD and exercise trial. Different and the interact CRP number of the contraindication. The treatment thus the conduct of following a minimum of 12 weeks of treatment and no later than 4 weeks from the conseptible reason. The authority application must be deemed to have failed this course of treatment in this treatment cycle. The authority application must be deemed to have failed this course of treatment in the treatment cycle. The authority application must be deemed to have failed this course of treatment in the reason must be stade in the application of the treatment to the reason must be determined to the application - Supporting Information Form which seeds details of the contraindication or intolerance and correl and the interact and the program staff condent in the streatment cycle. The authority application must be determined to the application - Supp					
If freatment 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 with MSAIDs is contraindicating to provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an dequate response to NSAIDs and must be demonstrated at the time of the initial application: (a) a Bath Ankylosing Spondylits 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 cessing NSAID treatment. If angl or higher daily (or periode cold within the application. If the requirement to demonstrate an elevated CRP level cuild not be met; the reason must be stated in the application. If the requirement to demonstrate an elevated CRP level cuild not be met; the reason must be stated in the application. If the requirement to demonstrate an elevated CRP level cuild not be met; the reason must be stated in the application. If the requirement to demonstrate an elevated CRP level cuild not be met; the reason must be stated in the application. If the requirement to demonstrate and elevated CRP level cuild not be met; the reason must be stated in the application. The assessment of the patient messures must be no more than 4 weeks do at the time at month (intramuscular or intravenous methylprednisione or theat integative course of treatment in this treatment cycle. The authority application must be under in writing and must include. (in a baseline BASDAI score; and (i) the residological report contring the absence of Grade III bateral sacroliitits; and (ii) a baseline C-r					
must provide details of the contraindication.must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity of the 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 Anklyosing 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 Pr 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 of at the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenterial steriod within the past month (Intramuscular or intravenous methylpredialis 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 Non-radiographic axial spondyloarthritis initial PSS Authority Application - Supporting Information Form which seeks details of (i) the radiological report confirming the absence of Grade II bilateral sacrollitis or Grade III or IV unilateral saccollitis; and (ii) a baseline C-raceture protein (CRP) level; and (V) the NSAID dose is less that the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication or intelerance according to the relevant TGA-approved Product Information more during the level must have cedve pror PSS-subsidised treatment win					
Image: the set of					
Image: Second					
LetInitial application: (a) a Bath Ankytosing 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 must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be scaled in the application. The assessment of the patient's response to the initial course of treatment must be scaled in the application. The assessment of the patient's response to the initial course of treatment in this treatment (site). The authority application must be stated reason. The assessment of the patient's response to the initial course of treatment in this treatment cycle. The authority application must be made in writing and must include: (a) 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 sacrolilitis or Grade III or IV unilateral sacrolilitis; and (ii) a baseline BASDAI score; and CRP) level; and (iii) a baseline C-reactive protein (CRP) level; and (iv) the MRI report; and (v) the MRI report; and correling to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the con				treatment withdrawal, the application must provide details of the nature and severity of this intolerance.	
(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 must be determined at the completion of the 3-month NSAID and exercise trial, but prot to ceasing NSAID treatment. All measures must be no more than 4 weeks 0 dat 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 prechisolone dosed at 7.5 mg or higher daily (or equivalent) to a parenteral steroid within the past month (intravenous methylpredhisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of 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 assessment of the patient's response to the initial course of the attent ourse. 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 assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment or supporting Information Form which seeks details of: (i) the redological report confirming the absence of Grade II bilateral sacrollitits or Grade III or IV unilateral sacrollitits; and (ii) a baseline BASDAI score; and (iii) a baseline C-reactive protein (CRP) level; and (iii) a baseline BASDAI score and CRP level must also be documented in the patient's medical records.Compliance with Writeen Autority Required protecut Information or sub te included.Compliance wi					
(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) to ra parenteral steroid within the past month (intravenous methy)prednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment nust be conducted following a minimum of 12 weeks of treatment in these timeframes, the patient wills 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 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 sacrolilitis or Grade III or IV unilateral sacrolilitis; and (ii) a baseline BASDAI score; and CRP level; and (w) the MRI report; and (w) the MRI reatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have neal cheven the suboly approved Product Information or testia of the contraindication or intolarence according to the relevant TGA-approved Product Information or testia of the contraindication or intolarence according to the relevant TGA-approved Product Information or testia of the contraindication or intolarence according to the re					
The baseline BASDAI score and CRP level must be determined at the completion of the 3-month NSAD and exercise trial, but proto to casing NSAD transment. All measures must be no more than 4 weeks old at the time of initial application. Treatment with predisiolone does at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the papt month (inframuscular or intravenous methylpredisiolene or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment nust 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 nuthority prescription form; and (i) a baseline C-reactive protein (CRP) level; and (iv) a completed Exercise Program Self Certification Form included in the supporting information form; and (iv) a completed Exercise Program Self Certification Form included in the supported product Information on details of the contraindication or intolated Exercise Program Self Certification Form included in the supported Information must be included.Compliance with written Authority Applicable reason.C10480P10480Non-radiographic axial spondyloarthritis initial reatment - Initial 3 (Recommencement of treatment and be alter a break in biological medicine of more than 5 years) Patient must have had a break in the tervent TGA-approved Product Information or details of the contraindication or intolatence according to the relevant TGA-approved Product Information must be included.					
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 pasts month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patients' 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 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 sacrolilitis or Grade III or IV unilateral sacrolilitis; and (ii) a baseline CASDAI score; and (iii) a baseline CASDAI score; and (iii) a baseline CASDAI score; and (iv) the MRI report; add (vi) the MRI report; add (vi) the MRI report; add (vi) the MRI report; add (vii) the RASID desi 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 reducted. The baseline BASDAI score and CRP level must also be documented in the patient's medical records.Compliance with Written Authority Required proced under the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information and etails 					
If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with predhisolone dosed at 7.5 mg or higher daily (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 curcle. 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 sacrolilitis or Grade III or IV unilateral sacrolilitis; and (ii) a baseline BASDAI score; and (iii) a baseline C-reactive protein (CRP) level; and (iv) a completed Non-radiographic axial spondyloarthritis initial PBS Authority Application must be included. The MSAID 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 or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the cont					
Image: Second					
Image: Second					
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 timefames, 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 preprintipation 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 sacrolliitis or Grade III or IV unilateral sacrolliitis; and (ii) 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 NSAID 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 or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details Intel 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 chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; ANDCompliance with Written Authority Required procedures					
Image: Second 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 sacrolliitis or Grade III or IV unilateral sacrolliitis; and (ii) 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 (v) the MRI report; and (v) the MSAID strailed, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used where the NSAID brailed, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used where the NSAID brailed, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used where the NSAID brailed, their doses and duration of treatment trad-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information and be included. The baseline BASDAI score and CRP level inust also be documented in the patient's medical records.Compliance with Written Authority Required proceduresC10480P10480Non-radiographic axial spondyloarthritis Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) 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 medi				The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12	
The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) 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 (iii) 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 MSAIDS 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.Compliance with Written Authority Required proceduresC10480P10480Non-radiographic axial spondyloarthritis Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have had a break in treatment of 5 years 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					
(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 II or IV unilateral sacroiliitis; and (ii) a baseline BASDAI score; and (iv) a completed Exercise Program Self Certification Form included in the supporting information form; and (v) the MRI report; and (v) the MRI report; and (v) the MRI report; and (v) the MRI report; and (v) the seline C-reactive protein (CRP) level; and (v) the MRI report; and (v) the BASDAI score and CRP level must also be documented in the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information and the baseline C-resonand CRP level must also be documented in the patient's medical records.Compliance with Written Authority Required proteint must have had chronic lower back pain and stiffness for 3 or more months that is relieved by exercise but not rest; ANN 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; ANDCompliance with written Authority Required procedures					
(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 sacrolliitis or Grade III or IV unilateral sacrolliitis; 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 (v) the MRI report; and (v) the MRI report; and (vi) the NSAID strialled, 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 or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information Patient must have received prior PBS-subsidised treatment if a biological medicine of more than 5 years) 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; ANDCompliance with Written Authority Required procedures					
which seeks details of:which seeks details of:which seeks details of: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 BASDAI score; and(iii) a baseline C-reactive protein (CRP) level; 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 NSAID strialled, 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 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.Compliance with Written Authority Required procedures protein CRP level must also be documented in the patient's medical records.Compliance with Written Authority Required procedures patient must have neceived prior PBS-subsidised treatment with a biological medicine of more than 5 years) 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; ANDCompliance with Written Authority Required procedures					
Image: Constraint of the contraint of the					
(ii) a baseline BASDAI score; and(iii) a baseline C-reactive protein (CRP) level; 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(v) the NSAIDs trialled, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used wherethe NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or detailsof 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.C10480P10480Non-radiographic axial spondyloarthritis Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years) Patient must have neceived prior PBS-subsidised treatment with a biological medicine for this condition; ANDPatient 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					
Image: constraint of the second sec					
Image: state in the state in					
(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.Compliance with Written Authority Required procedured product Information; ANDCompliance with Written Authority Required procedures 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; ANDCompliance with Written Authority Required procedures					
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.Compliance with Written Authority Required procedured prior PBS-subsidised treatment of treatment after a break in biological medicine of more than 5 years) 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; ANDCompliance with Written Authority Required procedures					
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.C10480P10480Non-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 a break in treatment of 5 years 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; ANDCompliance with Written Authority Required procedures					
C10480P10480Non-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 a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition; ANDCompliance with Written Authority Required procedures					
C10480 P10480 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					
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				The baseline BASDAI score and CRP level must also be documented in the patient's medical records.	
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		C10480	P10480	Non-radiographic axial spondyloarthritis	Compliance with Written
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					Authority Required
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					procedures
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					
medicine for this condition; AND					
	Instrument Number		f 2020		

		<ul> <li>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</li> <li>The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis; AND</li> <li>The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND</li> <li>The condition must be sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI); AND</li> <li>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</li> <li>The condition must have BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium); AND</li> <li>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.</li> <li>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</li> <li>The following must be stated in this application and documented in the patient's medical records:</li> <li>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and</li> <li>(b) C-reactive protein (CRP) level greater than 10 mg per L.</li> <li>The BASDAI score and CRP level must be no more than 4 weeks old at the time of this application.</li> <li>If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application.</li> <li>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.</li> <li>The assessment of the patient's response to the initial course</li></ul>	
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 exceeded 12 months from the date of this application. The full name of the medical practitioner. A review must have been planned to take place within 3 months from the date of this application. Authority requests extending treatment duration up to 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 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	The condition must require daily, continuous, long term therapy with this treatment; AND Patient must not be opioid naive; AND	
--------	--	--

	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	<ul> <li>Non-radiographic axial spondyloarthritis Continuing treatment</li> <li>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</li> <li>Patient must have demonstrated an adequate response to treatment with this drug for this condition; AND</li> <li>The treatment must not exceed a maximum of 24 weeks with this drug per authorised course under this restriction.</li> <li>Patient must be aged 18 years or older.</li> <li>Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis.</li> <li>An adequate response to therapy with this drug is defined as a reduction from baseline in the Bath Ankylosing Spondylitis</li> <li>Disease Activity Index (BASDAI) score by 2 or more units (on a scale of 1-10) and 1 of the following:</li> <li>(a) a CRP measurement no greater than 10 mg per L; or</li> <li>(b) a CRP measurement reduced by at least 20% from baseline.</li> <li>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.</li> <li>The 5-year break is measured from the approved date of the last prescription for PBS-subsidised treatment with this drug for this condition under the Initial 2 - Recommence of treatment after a break of more than 5 years.</li> <li>The patient meanis eligible to receive continuing treatment with this drug for this condition under the Initial 2 - Recommencent of treatment after a break of less than 5 years may re-commence a further course of treatment with this drug for this condition under the Initial 2 - Recommencent of treatment after a break of less than 5 years may re-commence a further course of treatment with the drug in courses of up to 24 weeks providing they continue to sustain the response. It is</li></ul>	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

C8223 P8	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	Compliance with Written Authority Required procedures
	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 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 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	
C8224 P8		Compliance with Writter Authority Required procedures

· · · · · · · · · · · · · · · · · · ·		r		1
			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.	
	C000E	D0005	Non radiographia avial apandulaarthritia	Compliance with
	C8225	P8225	Non-radiographic axial spondyloarthritis	Compliance with
			Continuing and Grandfathered treatment - balance of supply	Authority Required
			Patient must have received insufficient therapy with this drug under the Initial 3 (grandfathered patient) restriction to complete	
Instrument Number	r PB 42 oi	t 2020	40	

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 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; AND The condition must not be radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacroilitis 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 treated by a cheumatologist; CR Must be treated by a cheumatologist; CR Must be treated by a cheumatologist; CR 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 I	procedures
If freatment 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 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 or treatment and submitted no later than 4 weeks from the cessation of tha 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 twice, they must have, at a minimum, a 5-year break in pBS-subsidised 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 twice, they must have, at a minimum, a 5-year break in pBS-subsidised 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 twice, they must have, at a minimum, a 5-year break in pBS-subsidised treatment with this drug for the scub	F

	<ul> <li>this condition to the date of the first application for initial treatment under the Initial 1 restriction.</li> <li>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.</li> <li>The authority application must be made in writing and must include: <ul> <li>(a) a completed authority prescription form; and</li> <li>(b) a completed Non-radiographic axial spondyloarthritis initial PBS Authority Application - Supporting Information Form which must include the following:</li> <li>(i) a copy of the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and</li> <li>(ii) a copy of C-reactive protein (CRP) test result which must not be more than 1 month old at the time of application; and</li> <li>(iv) a completed Exercise Program Self Certification Form included in the supporting information form; and</li> <li>(v) a copy of the MRI report; and</li> <li>(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</li> </ul></li></ul>	
--	---	--

#### (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	<ul> <li>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 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 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.</li></ul>	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 contraindication. 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. 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 reatment 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 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 sacroilitis or Grade III or IV unilateral sacroilitis; and (ii) a baseline BASDAI score; a	
C10	0436	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; OR Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of 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
Instrument Number PE		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 43	Compliance with Written Authority Required procedures

Initial treatment - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years)       Authority Required         Patient must have neceviced prior PDS-subsidised treatment with a biological medicine for this condition; AND       Authority Required         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       Authority Required         Patient must have one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) posriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukoryce Antigen B27 (HLA-B27), AND       The condition must have hot be radiographically evidenced on plain x-ray of Grade II biateral sacroliititis. AND         The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND       The condition must be sacroliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MR); AND         The condition must have bas accolisitis with active inflammation and/or oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent); AND         The treatment must not exceed a maximum of 16 weeks duration under this restriction.         Patient must be seared by a neumologist; the experise 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	C104	490 P	10490	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. Non-radiographic axial spondyloarthritis	Compliance with Written
Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years) Authority Required		490 P	10490	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 sacrolliitis or Grade III or IV unilateral sacrollitin; AND The condition must be non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria; AND The condition must be sacrolliitis 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 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. Treatment with	Authority Required
	C104	491 P <sup>.</sup>	10491	Initial treatment - Initial 2 (Change or re-commencement of treatment after a break of less than 5 years)	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	procedures
	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	
	Imedicine: 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	

#### Schedule 4, Part 1, entry for Hydromorphone

substitute:

C10439	P10439	Severe pain	
		Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-	
		The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide	
		inadequate management of pain relief; OR	
		(i) severe disabling pain associated with proven malignant neoplasia; or	
		has exceeded 12 months and the patient's pain management and clinical need for continuing opioid treatment has been	
		(iv) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has	
		planned consultation are to be provided at the time of the application.	
		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	
		The condition must be such that maximum tolerated doses of non-opioid and other opioid analgesics would provide	
C10448		Chronic severe pain	Compliance with
			Authority Required procedures -
		Patient must have pain directly attributable to cancer; OR	Streamlined Authority
		Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-	Code 10448
		inadequate management of pain relief; OR	
		(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	
-	C10440		C10440         Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid and other opioid analgesics: would provide inadequate management of pain relief CR           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 disabiling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or           (ii) chronic severe disabiling pain where the total duration of non-PBS and PBS-subsidised opioid reatment has been in reviewed and confirmed through consultation with the patient by another medical practitioner. The review must have been in the past 12 months and the patient's pain management and clinical need for continuing opioid treatment has exceeded 12 months and the patient's pain management and clinical need for continuing opioid treatment has exceeded 12 months and the patient's pain management and elinical need for continuing opioid treatment has exceeded 12 months and the patient's pain management and the need contractitioner. The review must have been in the past 12 months in the the application. The full medical practitioner and the date of the palent's pain management and the contractitioner. A review must have been planned to take place within 3 months from the date of the saptication. A submit medical practitioner. A review must have been planned to take place within 3 months from the date of the saptication. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or by caling Services Austalia.           C10440         P10440         Severe pain           Pat

Instrument Number PB 42 of 2020

[92]

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

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

C10441		Compliance with
	The condition must require daily, continuous, long term therapy with this treatment; AND	Authority Required
	Patient must not be opioid naive; AND	procedures -
	Patient must have pain directly attributable to cancer; OR	Streamlined Authority
	Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non- opioid and other opioid analgesics; OR	Code 10441
	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	

treatment and up to 2 repeats).		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 the treatment and up to 2 months)	
---------------------------------	--	--	--

## [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 P104	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 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.	
Instrument Number DD 42 of 2020	40	

C10440	) P10440	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). 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	5	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 the application. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities sy	
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	6 P10466	Chronic severe disabling pain The condition must require daily, continuous, long term therapy with this treatment; AND	Compliance with Authority Required

ГТ	T			, , , , , , , , , , , , , , , , , , ,
			Patient must have pain directly attributable to cancer; OR	procedures
			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) observing accurate disabiling pain where the total duration of non DBS and DBS subsidized entired analysis treatment will an	
			(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).	
(	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 associated with proven malignant neoplasia, or (iii) 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.	
la star an interior	DD (0 (		Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities	
Instrument Number	PR 42 of	2020	50	

		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 On	
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:* Instrument Number PB 42 of 2020

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 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 plann	
	C10445		Patient must have pain directly attributable to cancer; OR	Compliance with Authority Required procedures - Streamlined Authority Code 10445

			<ul> <li>(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.</li> <li>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).</li> </ul>	
c	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 beyond 1 month may be requested t	
C	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	<ul> <li>opioid or other opioid analgésics; OR</li> <li>The condition must be such that maximum tolerated doses of non-opioid or other opioid analgesics would provide inadequate management of pain relief; OR</li> <li>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: <ul> <li>(i) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or</li> <li>(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</li> <li>(iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 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</li> <li>(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</li> </ul> </li> </ul>	
		(iii) chronic severe disabling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has	

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

substitute:

Tapentadol	C10445	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-	Compliance with Authority Required procedures - Streamlined Authority Code 10445
		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).	
--	--	--

## [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 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. Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment durat	

		treatment and up to 2 repeats).	
C10445		<ul> <li>Chronic severe pain</li> <li>The condition must require daily, continuous, long term therapy with this treatment; AND</li> <li>Patient must have pain directly attributable to cancer; QR</li> <li>Patient must have previously experienced inadequate management of pain relief following maximum tolerated doses of non-opioid or other opioid analgesics; OR</li> <li>The condition must be such that maximum tolerated doses of non-opioid or other opioid analgesics would provide inadequate management of pain relief; OR</li> <li>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:</li> <li>(i) chronic severe disabiling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment is less than 12 months; or</li> <li>(ii) chronic severe disabiling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment by another medical practitioner, 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 mamed inmediately 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</li> <li>(iii) chronic severe disabiling pain where the total duration of non-PBS and PBS-subsidised opioid analgesic treatment has exceeded 12 months and the total duration of non-PBS and PBS-subsidised opioid analgesic treatment and the adte of the most recent consultation are to be provided at the time of each application; or</li> <li>(iii) chronic severe disabiling 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 manag</li></ul>	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:

Т	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
Instrument I	Number PB 42 of 2020	57

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
lloprost	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
Instrument Nu	mber PB 42 of 2020	59

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
Instrument N	umber PR 42 of 2020	60

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	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