**PB 86 of 2023**

# National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 9)

*National Health Act 1953*

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

Dated 30 August 2023

**NIKOLAI TSYGANOV**
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division

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# Contents

## 1 Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 9)*.

(2) This Instrument may also be cited as PB 86 of 2023.

## 2 Commencement

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

| **Commencement information** | | |
|---|---|---|
| **Column 1** | **Column 2** | **Column 3** |
| **Provisions** | **Commencement** | **Date/Details** |
| 1. *The whole of this instrument* | Immediately after the commencement of the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 8)* (PB 79 of 2023). | |

Note: This table relates only to the provisions of this instrument as originally made.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

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

## 3 Authority

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

## 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

# Schedule 1—Amendments

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

**[1]** **Schedule 1, Part 1, entry for Acalabrutinib in each of the forms: Capsule 100 mg; and Tablet 100 mg**

**(a)** *omit from the column headed "Circumstances":* **C10652 C12481**

**(b)** *insert in numerical order in the column headed "Circumstances":* **C14344**

**[2]** **Schedule 1, Part 1, entry for Alendronic acid with colecalciferol in the form Tablet 70 mg (as alendronate sodium) with 70 micrograms colecalciferol**

*omit:*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | a | FonatPlus | AF | MP NP | C6307 C6315 C6320 | 4 | 5 | 4 |

**[3]** **Schedule 1, Part 1, entry for Alendronic acid with colecalciferol in the form Tablet 70 mg (as alendronate sodium) with 140 micrograms colecalciferol**

*omit:*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | a | FonatPlus | AF | MP NP | C6306 C6319 C6325 | 4 | 5 | 4 |

**[4]** **Schedule 1, Part 1, entry for Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides**

*insert as first entry:*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Oral powder with 2'-fucosyllactose and lacto-N-neotetraose, 400 g (Alfamino) | Oral | | Alfamino | NT | MP NP | C4305 C4312 C4323 C4330 C4337 C4338 C4339 C4345 C4352 C4415 C5945 C5974 | 8 | 5 | 1 |

**[5]** **Schedule 1, Part 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *[Maximum Quantity: 10; Number of Repeats: 0]***

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | a | Alphaclav Duo Viatris | AL | MP NP | C5832 C5893 C10405 | P5832 P5893 | 10 | 0 | 10 |
| | | | | MW | C5832 C5893 | | 10 | 0 | 10 |
| | | | | PDP | C5833 C5894 | | 10 | 0 | 10 |

**[6] Schedule 1, Part 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *[Maximum Quantity: 20; Number of Repeats: 0]***

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | a | Alphaclav Duo Viatris | AL | MP NP | C5832 C5893 C10405 | P10405 | 20 | 0 | 10 |

**[7] Schedule 1, Part 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *[Maximum Quantity: 10; Number of Repeats: 0]***

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Alphaclav Duo Forte Viatris | AL | MP NP | C5832 C5893 C10413 | P5832 P5893 | 10 | 0 | 10 |
| | | | | PDP | C5833 C5894 | | 10 | 0 | 10 |

**[8] Schedule 1, Part 1, entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *[Maximum Quantity: 20; Number of Repeats: 0]***

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Alphaclav Duo Forte Viatris | AL | MP NP | C5832 C5893 C10413 | P10413 | 20 | 0 | 10 |

**[9] Schedule 1, Part 1, entry for Anastrozole**

*omit:*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | a | Anastrozole FBM | FO | MP NP | C5464 | | 30 | 5 | 30 |

**[10] Schedule 1, Part 1, entry for Apomorphine**

*omit:*

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Injection containing apomorphine hydrochloride hemihydrate 20 mg in 2 mL | Injection | | Movapo | TD | MP NP | C10844 | 360 | 5 | 5 | |
| | | | | | | MP | C11385 C11445 | 360 | 5 | 5 | C(100) |

**[11] Schedule 1, Part 1, entry for Aripiprazole in each of the forms: Tablet 10 mg; Tablet 15 mg; and Tablet 20 mg**

*omit:*

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | a | Aripiprazole generichealth | HQ | MP NP | C4246 | 30 | 5 | 30 | |

**[12] Schedule 1, Part 1, entry for Azacitidine in the form Powder for injection 100 mg**

*omit from the column headed "Section 100/ Prescriber Bag only" (all instances):* **D(100)** *substitute:* **PB(100)**

**[13] Schedule 1, Part 1, after entry for Azacitidine in the form Powder for injection 100 mg**

*insert:*

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Tablet 200 mg | Oral | Onureg | CJ | MP | C14338 | 14 | 2 | 7 | |
| | Tablet 300 mg | Oral | Onureg | CJ | MP | C14323 C14332 P14332 P14338 C14338 | 14 | 2 | 7 | |
| | | | | | MP | C14323 C14332 P14323 C14338 | 21 | 1 | 7 | |

**[14] Schedule 1, Part 1, entry for Bendamustine in each of the forms: Powder for injection containing bendamustine hydrochloride 25 mg; and Powder for injection containing bendamustine hydrochloride 100 mg**

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

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Bendamustine Juno | JU | MP | C7943 C7944 C7972 | See Note 3 | See Note 3 | 1 | D(100) |

**[15] Schedule 1, Part 1, entry for Chlorpromazine**

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

**[16]** **Schedule 1, Part 1, entry for Clonidine in the form Tablet containing clonidine hydrochloride 100 micrograms *[Maximum Quantity: 100; Number of Repeats: 5]***

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

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | a | Clonidine Lupin | GQ | MP NP | | | 100 | 5 | 100 | |

**[17]** **Schedule 1, Part 1, entry for Entecavir in the form Tablet 1 mg (as monohydrate)**

*omit:*

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | a | Entecavir GH | GQ | MP NP | C5037 C5044 | | 60 | 5 | 30 | D(100) |

**[18]** **Schedule 1, Part 1, entry for Escitalopram in the form Tablet 10 mg (as oxalate)**

*omit from the column headed "Circumstances" for the brand "LoxaLate":* **C4755** *substitute:* **C4690 C4703 C4755 C4756 C4757**

**[19]** **Schedule 1, Part 1, entry for Everolimus in the form Tablet 5 mg**

*substitute:*

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Tablet 5 mg | Oral | Afinitor | NV | MP | C4351 C4812 C4837 C4861 C7431 C7432 C8622 | P4861 P8622 | 30 | 2 | 30 | |
| | | | | | MP | C4351 C4812 C4837 C4861 C7431 C7432 C8622 | P4351 P4812 P4837 P7431 P7432 | 30 | 5 | 30 | |

**[20]** **Schedule 1, Part 1, entry for Everolimus in the form Tablet 10 mg**

*substitute:*

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Tablet 10 mg | Oral | Afinitor | NV | MP | C4351 C4812 C4837 C4861 C7431 C7432 C8622 | P4861 P8622 | 30 | 2 | 30 | |
| | | | | | MP | C4351 C4812 C4837 C4861 C7431 C7432 C8622 | P4351 P4812 P4837 P7431 P7432 | 30 | 5 | 30 | |

**[21] Schedule 1, Part 1, entry for Fingolimod in the form Capsule 500 micrograms (as hydrochloride)**

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | a | Fingolimod Sandoz | SZ | MP | C10162 C10172 | 28 | 5 | 28 |

**[22] Schedule 1, Part 1, after entry for Glucagon in the form Injection set containing glucagon hydrochloride 1 mg (1 I.U.) and 1 mL solvent in disposable syringe**

*insert:*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Injection set containing glucagon hydrochloride 1 mg (1 I.U.) and 1 mL solvent in disposable syringe (s19A) | Injection | GlucaGen Hypokit (Germany) | DZ | PDP | | 1 | 0 | 1 |
| | | | | | MP NP | | 1 | 1 | 1 |

**[23] Schedule 1, Part 1, entry for Ibrutinib in the form Capsule 140 mg *[Maximum Quantity: 90; Number of Repeats: 5]***

**(a)** *omit from the column headed "Circumstances":* **C7858 C12472**

**(b)** *insert in numerical order in the column headed "Circumstances":* **C14344**

**(c)** *omit from the column headed "Purposes":* **P7858 P12472** *substitute:* **P14344**

**[24] Schedule 1, Part 1, entry for Ibrutinib in the form Capsule 140 mg *[Maximum Quantity: 120; Number of Repeats: 5]***

**(a)** *omit from the column headed "Circumstances":* **C7858 C12472**

**(b)** *insert in numerical order in the column headed "Circumstances":* **C14344**

**[25] Schedule 1, Part 1, entry for Idelalisib in each of the forms: Tablet 100 mg; and Tablet 150 mg**

**(a)** *omit from the column headed "Circumstances":* **C12479**

**(b)** *insert in numerical order in the column headed "Circumstances":* **C14346**

**[26] Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate)**

**(a)** *omit:*

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Imatinib GH | GQ | MP | C9203 C9204 C9206 C9207 C9209 C9238 C9240 C9243 | P9203 P9207 P9319 P12525 P12527 P12542 P12543 P13132 | 60 | 2 | 60 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | C9274 C9276<br>C9278 C9296<br>C9319 C12525<br>C12527 C12536<br>C12541 C12542<br>C12543 C13132 | | | | |

**(b)** *omit:*

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Imatinib GH | GQ | MP | C9203 C9204<br>C9206 C9207<br>C9209 C9238<br>C9240 C9243<br>C9274 C9276<br>C9278 C9296<br>C9319 C12525<br>C12527 C12536<br>C12541 C12542<br>C12543 C13132 | P9204 P9206<br>P9209 P9238<br>P9240 P9243<br>P9274 P9276<br>P9278 P9296<br>P12536 P12541 | 60 | 5 | 60 |

**[27] Schedule 1, Part 1, entry for Letrozole**

*omit:*

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | a | Letrozole FBM | FO | MP NP | C5464 | | 30 | 5 | 30 |

**[28] Schedule 1, Part 1, entry for Levothyroxine**

*substitute:*

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Levothyroxine | Tablet containing 50 micrograms anhydrous levothyroxine sodium | Oral | a | APO-Levothyroxine | XT | MP NP | | | 200 | 1 | 200 |
| | | | b | Eltroxin | LT | MP NP | | | 200 | 1 | 200 |
| | | | a | Eutroxsig | LN | MP NP | | | 200 | 1 | 200 |
| | | | b | Levothox | AF | MP NP | | | 200 | 1 | 200 |
| | | | a | Levothyroxine Lup | GQ | MP NP | | | 200 | 1 | 200 |
| | | | a | LEVOXINE | RA | MP NP | | | 200 | 1 | 200 |
| | | | a | Oroxine | AS | MP NP | | | 200 | 1 | 200 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Tablet containing 75 micrograms anhydrous levothyroxine sodium | Oral | a | APO-Levothyroxine | XT | MP NP | 200 | 1 | 200 |
| | | b | Eltroxin | LT | MP NP | 200 | 1 | 200 |
| | | a | Eutroxsig | LN | MP NP | 200 | 1 | 200 |
| | | b | Levothox | AF | MP NP | 200 | 1 | 200 |
| | | a | Levothyroxine Lup | GQ | MP NP | 200 | 1 | 200 |
| | | a | LEVOXINE | RA | MP NP | 200 | 1 | 200 |
| | | a | Oroxine | AS | MP NP | 200 | 1 | 200 |
| Tablet containing 100 micrograms anhydrous levothyroxine sodium | Oral | a | APO-Levothyroxine | XT | MP NP | 200 | 1 | 200 |
| | | b | Eltroxin | LT | MP NP | 200 | 1 | 200 |
| | | a | Eutroxsig | LN | MP NP | 200 | 1 | 200 |
| | | b | Levothox | AF | MP NP | 200 | 1 | 200 |
| | | a | Levothyroxine Lup | GQ | MP NP | 200 | 1 | 200 |
| | | a | LEVOXINE | RA | MP NP | 200 | 1 | 200 |
| | | a | Oroxine | AS | MP NP | 200 | 1 | 200 |
| Tablet containing 125 micrograms anhydrous levothyroxine sodium | Oral | | Eltroxin | LT | MP NP | 200 | 1 | 200 |
| Tablet containing 200 micrograms anhydrous levothyroxine sodium | Oral | a | APO-Levothyroxine | XT | MP NP | 200 | 1 | 200 |
| | | b | Eltroxin | LT | MP NP | 200 | 1 | 200 |
| | | a | Eutroxsig | LN | MP NP | 200 | 1 | 200 |
| | | b | Levothox | AF | MP NP | 200 | 1 | 200 |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | a | Levothyroxine Lup | GQ | MP NP | | | 200 | 1 | 200 | |
| | | | | a | LEVOXINE | RA | MP NP | | | 200 | 1 | 200 | |
| | | | | a | Oroxine | AS | MP NP | | | 200 | 1 | 200 | |

**[29] Schedule 1, Part 1, entry for Methotrexate in the form Injection 50 mg in 2 mL vial**

*substitute:*

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Injection 50 mg in 2 mL vial | Injection | DBL Methotrexate | PF | MP | | | 5 | 5 | 5 | | |
| | | | | | MP | | | See Note 2 | See Note 2 | 5 | | C(100) |
| | | | | | MP | | P6276 | See Note 2 | See Note 2 | 5 | | C(100) |

**[30] Schedule 1, Part 1, entry for Mifepristone and misoprostol**

*omit from the column headed "Authorised Prescriber":* **MP NP** *substitute:* **MP NP MW**

**[31] Schedule 1, Part 1, after entry for Naloxone in the form Nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2**

*insert:*

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2 (s19A) | Nasal | Nyxoid (UK) | QY | PDP MP NP | | | 1 | 0 | 1 | | |

**[32] Schedule 1, Part 1, entry for Obinutuzumab**

**(a)** *omit from the column headed "Circumstances":* **C11052**

**(b)** *insert in numerical order in the column headed "Circumstances":* **C14326**

**[33] Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[Maximum Quantity: 4; Number of Repeats: 0]***

*omit:*

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Ondansetron ODT Lupin | HQ | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 | | |
| | | | | | MP | C5743 | | 4 | 0 | 4 | | C(100) |

**[34]** **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg *[Maximum Quantity: 10; Number of Repeats: 1]***

**(a)** *omit from the column headed "Circumstances" for the brand "Ondansetron ODT Lupin":* **C5618**

**(b)** *omit from the column headed "Purposes" for the brand "Ondansetron ODT Lupin":* **P10498**

**[35]** **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[Maximum Quantity: 4; Number of Repeats: 0]***

*omit:*

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Ondansetron ODT Lupin | HQ | MP NP | C5618 C10498 | P5618 | 4 | 0 | 4 | |
| | | | | | | MP | C5743 | | 4 | 0 | 4 | C(100) |

**[36]** **Schedule 1, Part 1, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[Maximum Quantity: 10; Number of Repeats: 1]***

**(a)** *omit from the column headed "Circumstances" for the brand "Ondansetron ODT Lupin":* **C5618**

**(b)** *omit from the column headed "Purposes" for the brand "Ondansetron ODT Lupin":* **P10498**

**[37]** **Schedule 1, Part 1, entry for Ondansetron in the form Wafer 4 mg**

*substitute:*

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Wafer 4 mg | Oral | | Zofran Zydis | AS | MP NP | C10498 | | 10 | 1 | 10 |

**[38]** **Schedule 1, Part 1, entry for Oxazepam**

*substitute:*

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Oxazepam | Tablet 15 mg | Oral | a | Alepam 15 | AF | MP NP PDP | | | 25 | 0 | 25 |
| | | | a | Serepax | AS | MP NP PDP | | | 25 | 0 | 25 |
| | | | a | Alepam 15 | AF | MP NP | | P6176 | 50 CN6176 | 3 CN6176 | 25 |
| | | | a | Serepax | AS | MP NP | | P6176 | 50 CN6176 | 3 CN6176 | 25 |
| | | | a | Alepam 15 | AF | MP NP | | P6217 P6230 P6262 | 50 CN6217 CN6230 CN6262 | 5 CN6217 CN6230 CN6262 | 25 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | a | Serepax | AS | MP NP | P6217 P6230 P6262 | 50 CN6217 CN6230 CN6262 | 5 CN6217 CN6230 CN6262 | 25 |
| Tablet 30 mg | Oral | a | Alepam 30 | AF | MP NP PDP | | 25 | 0 | 25 |
| | | a | APO-Oxazepam | TX | MP NP PDP | | 25 | 0 | 25 |
| | | a | Murelax | RW | MP NP PDP | | 25 | 0 | 25 |
| | | a | Serepax | AS | MP NP PDP | | 25 | 0 | 25 |
| | | a | Alepam 30 | AF | MP NP | P6176 | 50 CN6176 | 3 CN6176 | 25 |
| | | a | APO-Oxazepam | TX | MP NP | P6176 | 50 CN6176 | 3 CN6176 | 25 |
| | | a | Murelax | RW | MP NP | P6176 | 50 CN6176 | 3 CN6176 | 25 |
| | | a | Serepax | AS | MP NP | P6176 | 50 CN6176 | 3 CN6176 | 25 |
| | | a | Alepam 30 | AF | MP NP | P6217 P6230 P6262 | 50 CN6217 CN6230 CN6262 | 5 CN6217 CN6230 CN6262 | 25 |
| | | a | APO-Oxazepam | TX | MP NP | P6217 P6230 P6262 | 50 CN6217 CN6230 CN6262 | 5 CN6217 CN6230 CN6262 | 25 |
| | | a | Murelax | RW | MP NP | P6217 P6230 P6262 | 50 CN6217 CN6230 CN6262 | 5 CN6217 CN6230 CN6262 | 25 |
| | | a | Serepax | AS | MP NP | P6217 P6230 P6262 | 50 CN6217 CN6230 | 5 CN6217 CN6230 | 25 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | CN6262 | CN6262 | |

**[39] Schedule 1, Part 1, after entry for Pasireotide in the form Injection (modified release) 60 mg (as embonate), vial and diluent syringe**

*insert:*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Patiromer | Powder for oral suspension 8.4 g | Oral | Veltassa | CS | MP | C14327 C14342 | 30 | 5 | 30 |
| | | | | | NP | C14327 | 30 | 5 | 30 |
| | Powder for oral suspension 16.8 g | Oral | Veltassa | CS | MP | C14327 C14342 | 30 | 5 | 30 |
| | | | | | NP | C14327 | 30 | 5 | 30 |

**[40] Schedule 1, Part 1, entry for Pembrolizumab**

*insert in numerical order in the column headed "Circumstances":* **C14324**

**[41] Schedule 1, Part 1, entry for Periciazine in each of the forms: Tablet 2.5 mg; and Tablet 10 mg**

*omit from the column headed "Responsible Person":* **SW** *substitute:* **IX**

**[42] Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 2.5 mg *[Maximum Quantity: 30; Number of Repeats: 5]***

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | APX-Perindopril Arginine | XT | MP NP | | 30 | 5 | 30 |

**[43] Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 5 mg *[Maximum Quantity: 30; Number of Repeats: 5]***

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | APX-Perindopril Arginine | XT | MP NP | | 30 | 5 | 30 |

**[44] Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 10 mg *[Maximum Quantity: 30; Number of Repeats: 5]***

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | APX-Perindopril Arginine | XT | MP NP | | | 30 | 5 | 30 |

**[45] Schedule 1, Part 1, entry for Perindopril with amlodipine in the form Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besilate) *[Maximum Quantity: 30; Number of Repeats: 5]***

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | a | APX-Perindopril Arginine/Amlodipine 5/5 | XT | MP NP | C4398 C4418 C14245 C14246 | P4398 P4418 | 30 | 5 | 30 |

**[46] Schedule 1, Part 1, entry for Perindopril with amlodipine in the form Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besilate) *[Maximum Quantity: 30; Number of Repeats: 5]***

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | a | APX-Perindopril Arginine/Amlodipine 5/10 | XT | MP NP | C4398 C4418 C14245 C14246 | P4398 P4418 | 30 | 5 | 30 |

**[47] Schedule 1, Part 1, entry for Perindopril with amlodipine in the form Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besilate) *[Maximum Quantity: 30; Number of Repeats: 5]***

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | a | APX-Perindopril Arginine/Amlodipine 10/5 | XT | MP NP | C4398 C4418 C14245 C14246 | P4398 P4418 | 30 | 5 | 30 |

**[48] Schedule 1, Part 1, entry for Perindopril with amlodipine in the form Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besilate) *[Maximum Quantity: 30; Number of Repeats: 5]***

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | a | APX-Perindopril Arginine/Amlodipine 10/10 | XT | MP NP | C4398 C4418 C14245 C14246 | P4398 P4418 | 30 | 5 | 30 |

**[49] Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 5 mg (as calcium) *[Maximum Quantity: 30; Number of Repeats: 5]***

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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | a | Blooms Rosuvastatin | BG | MP NP | 30 | 5 | 30 |

**[50]** **Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 10 mg (as calcium)** ***[Maximum Quantity: 30; Number of Repeats: 5]***

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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | a | Blooms Rosuvastatin | BG | MP NP | 30 | 5 | 30 |

**[51]** **Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 20 mg (as calcium)** ***[Maximum Quantity: 30; Number of Repeats: 5]***

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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | a | Blooms Rosuvastatin | BG | MP NP | 30 | 5 | 30 |

**[52]** **Schedule 1, Part 1, entry for Rosuvastatin in the form Tablet 40 mg (as calcium)** ***[Maximum Quantity: 30; Number of Repeats: 5]***

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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | a | Blooms Rosuvastatin | BG | MP NP | 30 | 5 | 30 |

**[53]** **Schedule 1, Part 1, omit entry for Saquinavir**

**[54]** **Schedule 1, Part 1, entry for Tofacitinib in the form Tablet 5 mg** ***[Maximum Quantity: 56; Number of Repeats: 3]***

**(a)** *omit from the column headed "Circumstances":* **C14207**

**(b)** *insert in numerical order in the column headed "Circumstances":* **C14345**

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

**(a)** *omit from the column headed "Circumstances":* **C14207**

**(b)** *insert in numerical order in the column headed "Circumstances":* **C14345**

**(c)** *omit from the column headed "Purposes":* **P14207**

**(d)** *insert in numerical order in the column headed "Purposes":* **P14345**

**[56]** **Schedule 1, Part 1, entry for Trastuzumab in the form Powder for I.V. infusion 150 mg**

*omit:*

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Ontruzant | OQ | MP | C9349 C9353<br>C9571 C9573<br>C10213 C10293<br>C10294 C10296 | See Note 3 | See Note 3 | 1 | PB(100) |

**[57] Schedule 1, Part 1, entry for Venetoclax in the form Pack containing 14 tablets venetoclax 10 mg and 7 tablets venetoclax 50 mg and 7 tablets venetoclax 100 mg and 14 tablets venetoclax 100 mg**

*omit from the column headed "Circumstances":* **C11053 C12482** *substitute:* **C14325 C14340**

**[58] Schedule 1, Part 1, entry for Zanubrutinib**

*insert in numerical order in the column headed "Circumstances":* **C14337 C14344**

**[59] Schedule 1, Part 2, omit entry for Chlorpromazine**

**[60] Schedule 1, Part 2, omit entry for Losartan**

**[61] Schedule 1, Part 2, omit entry for Norethisterone with mestranol**

**[62] Schedule 1, Part 2, omit entry for Piroxicam**

**[63] Schedule 1, Part 2, omit entry for Polyethylene glycol 400 with propylene glycol**

**[64] Schedule 1, Part 2, omit entry for Polyvinyl alcohol**

**[65] Schedule 1, Part 2, omit entry for Propranolol**

**[66] Schedule 3**

*omit:*

| | | |
|---|---|---|
| FO | For Benefit Medicines Pty Ltd | 56 155 126 346 |

**[67] Schedule 4, Part 1, entry for Acalabrutinib**

**(a)** *omit:*

| | | | | | |
|---|---|---|---|---|---|
| | C10652 | | | Relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Continuing treatment of relapsed or refractory CLL/SLL<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures |
| | C12481 | | | Relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) | Compliance with |

| | | | | | |
|---|---|---|---|---|---|
| | | | | Initial treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The condition must have relapsed or be refractory to at least one prior therapy; AND<br>Patient must have a WHO performance status of 1 or less; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must be considered unsuitable for treatment or retreatment with a purine analogue; AND<br>Patient must not have received treatment with another Bruton's tyrosine kinase (BTK) inhibitor for any line of treatment of CLL/SLL (untreated or relapsed/refractory disease); OR<br>Patient must have developed intolerance to another Bruton's tyrosine kinase (BTK) inhibitor of a severity necessitating permanent treatment withdrawal when being treated for relapsed or refractory CLL/SLL.<br>A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:<br>a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;<br>b) Age is 70 years or older;<br>c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;<br>d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;<br>e) Evidence of one or more 17p chromosomal deletions demonstrated by a Medicare Benefits Schedule listed test. | Authority Required procedures |

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

| | | | | | |
|---|---|---|---|---|---|
| | C14344 | | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Treatment of relapsed/refractory disease<br>The condition must have relapsed or be refractory to at least one prior therapy; AND<br>The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.<br>Patient must not be undergoing retreatment with this drug where prior, active treatment of CLL/SLL with this same drug was unable to prevent disease progression; AND<br>Patient must be undergoing treatment through this treatment phase listing for the first time; OR<br>Patient must be undergoing treatment through this treatment phase listing on a subsequent occasion, with disease progression being absent. | Compliance with Authority Required procedures |

**[68] Schedule 4, Part 1, after entry for Axitinib**

*insert:*

| | | | | | |
|---|---|---|---|---|---|
| Azacitidine | C14323 | P14323 | | Acute Myeloid Leukaemia<br>Dose escalation therapy - Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND | Compliance with Written Authority Required procedures |

| | | | | | |
|---|---|---|---|---|---|
| | | | | Patient must have, in order to extend the dose schedule as per the TGA-approved Product Information, between 5% to 15% blasts in either the: (i) bone marrow, (ii) peripheral blood, in conjunction with clinical assessment; AND<br>Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.<br>Authority applications must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail:<br>If the application is submitted through HPOS form upload or mail, it must include:<br>(a) a completed authority prescription form; and<br>(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)<br>(c) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating the blast percentage.<br>All reports must be documented in the patient's medical records. | |
| | C14332 | P14332 | | Acute Myeloid Leukaemia<br>Treatment following intensive induction chemotherapy - Initial treatment<br>Patient must have demonstrated either: (i) first complete remission, (ii) complete remission with incomplete blood count recovery following intensive induction chemotherapy; AND<br>Patient must not be a candidate for, including those who choose not to proceed to, haematopoietic stem cell transplantation; AND<br>Patient must have, at the time of induction therapy, a cytogenetic risk classified as either: (i) intermediate-risk, (ii) poor-risk; AND<br>Patient must not have undergone a stem cell transplant; AND<br>Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin.<br>A complete remission is defined as: bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood transfusions and a recovery of peripheral blood counts with peripheral neutrophil count greater than 1.0 x $10^{9}$ /L and platelet count greater than or equal to 100 x $10^{9}$ /L.<br>A complete remission with incomplete blood count recovery is defined as bone marrow blasts of less than 5%, absence of blasts with Auer rods, absence of extramedullary disease, independent of blood transfusions and a recovery of peripheral blood counts with peripheral neutrophil count less than 1.0 x $10^{9}$ /L or platelet count less than 100 x $10^{9}$ /L. | Compliance with Authority Required procedures |
| | C14338 | P14338 | | Acute Myeloid Leukaemia<br>Treatment following intensive induction chemotherapy - Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must have, for reasons not attributable to any cause other than AML, no more than 15% blasts in either the: (i) bone marrow, (ii) peripheral blood; AND<br>Patient must not be receiving concomitant PBS-subsidised treatment with midostaurin. | Compliance with Authority Required procedures |

**[69] Schedule 4, Part 1, entry for Ibrutinib**

**(a)** *omit:*

| | | | | | |
|---|---|---|---|---|---|
| | C7858 | P7858 | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Continuing treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND | Compliance with Authority Required procedures |

| | | | | | |
|---|---|---|---|---|---|
| | | | | Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition. | |
| | C12472 | P12472 | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Initial treatment<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The condition must have relapsed or be refractory to at least one prior therapy; AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have received treatment with another Bruton's tyrosine kinase (BTK) inhibitor for any line of treatment of CLL/SLL (untreated or relapsed/refractory disease); OR<br>Patient must have developed intolerance to another Bruton's tyrosine kinase (BTK) inhibitor of a severity necessitating permanent treatment withdrawal when being treated for relapsed or refractory CLL/SLL; AND<br>Patient must be considered unsuitable for treatment or retreatment with a purine analogue.<br>A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:<br>a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;<br>b) Age is 70 years or older;<br>c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen;<br>d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;<br>e) Evidence of one or more 17p chromosomal deletions demonstrated by a Medicare Benefits Schedule listed test. | Compliance with Authority Required procedures |

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

| | | | | | |
|---|---|---|---|---|---|
| | C14344 | P14344 | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Treatment of relapsed/refractory disease<br>The condition must have relapsed or be refractory to at least one prior therapy; AND<br>The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.<br>Patient must not be undergoing retreatment with this drug where prior, active treatment of CLL/SLL with this same drug was unable to prevent disease progression; AND<br>Patient must be undergoing treatment through this treatment phase listing for the first time; OR<br>Patient must be undergoing treatment through this treatment phase listing on a subsequent occasion, with disease progression being absent. | Compliance with Authority Required procedures |

**[70] Schedule 4, Part 1, entry for Idelalisib**

**(a)** *omit:*

| | | | | | |
|---|---|---|---|---|---|
| | C12479 | | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Initial treatment<br>The condition must be confirmed Chronic lymphocytic leukaemia (CLL) prior to initiation of treatment; OR<br>The condition must be confirmed Small lymphocytic lymphoma (SLL) prior to initiation of treatment; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be in combination with rituximab for up to a maximum of 8 doses under this restriction, followed by monotherapy for this condition; AND<br>The condition must have relapsed or be refractory to at least one prior therapy; AND<br>The condition must be CD20 positive; AND<br>Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage); AND<br>Patient must be inappropriate for chemo-immunotherapy.<br>The prescriber must provide the CIRS score at the time of application.<br>A patient can be considered inappropriate for chemo-immunotherapy when one or more of the following are experienced:<br>1. Severe neutropenia defined as absolute neutrophil count of less than or equal to 1.0 x $10^9$/L; or<br>2. Severe thrombocytopenia defined as platelet count of less than or equal to 50 x $10^9$/L; or<br>3. Evidence of one or more 17p chromosomal deletions demonstrated by a Medicare Benefits Schedule listed test.<br>A pathology report confirming the patient is inappropriate for chemo-immunotherapy must be documented in the patient's medical records and must be no more than 4 weeks old at the time of application. | Compliance with Authority Required procedures |

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

| | | | | | |
|---|---|---|---|---|---|
| | C14346 | | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Initial treatment<br>The condition must be confirmed Chronic lymphocytic leukaemia (CLL) prior to initiation of treatment; OR<br>The condition must be confirmed Small lymphocytic lymphoma (SLL) prior to initiation of treatment; AND<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be in combination with rituximab for up to a maximum of 8 doses under this restriction, followed by monotherapy for this condition; AND<br>The condition must have relapsed or be refractory to at least one prior therapy; AND<br>The condition must be CD20 positive; AND<br>The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition. | Compliance with Authority Required procedures |

## [71] Schedule 4, Part 1, entry for Obinutuzumab

**(a)** *omit:*

| | | | | | |
|---|---|---|---|---|---|
| | C11052 | | | Chronic lymphocytic leukaemia (CLL)<br>Combination use with chlorambucil only<br>The condition must be CD20 positive; AND<br>The condition must be previously untreated; AND<br>Patient must be inappropriate for fludarabine based chemo-immunotherapy; AND<br>The treatment must be in combination with chlorambucil; AND | Compliance with Authority Required procedures - Streamlined Authority Code 11052 |

| | | | | | |
|---|---|---|---|---|---|
| | | | | Patient must have a creatinine clearance 30 mL/min or greater; AND<br>Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage); OR<br>Patient must have a creatinine clearance less than 70 mL/min.<br>Treatment must be discontinued in patients who experience disease progression whilst on this treatment. | |

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

| | | | | | |
|---|---|---|---|---|---|
| | C14326 | | | Chronic lymphocytic leukaemia (CLL)<br>Combination use with chlorambucil only<br>The condition must be CD20 positive; AND<br>The condition must be previously untreated; AND<br>The treatment must be in combination with chlorambucil; AND<br>The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition.<br>Treatment must be discontinued in patients who experience disease progression whilst on this treatment. | Compliance with Authority Required procedures - Streamlined Authority Code 14326 |

**[72] Schedule 4, Part 1, after entry for Paroxetine**

*insert:*

| | | | | | |
|---|---|---|---|---|---|
| Patiromer | C14327 | | | Chronic hyperkalaemia<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not be in place of emergency treatment of hyperkalaemia; AND<br>Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor.<br>Patient must not be undergoing dialysis. | Compliance with Authority Required procedures - Streamlined Authority Code 14327 |
| | C14342 | | | Chronic hyperkalaemia<br>Initial PBS-subsidised treatment (including grandfathered patients)<br>Patient must have stage 3 to stage 4 chronic kidney disease.<br>The condition must be inadequately controlled by a low potassium diet.; AND<br>Patient must have experienced at least 2 episodes of hyperkalaemia (defined as serum potassium levels of at least 6.0 mmol/L) within the 12 months prior to commencing this drug; AND<br>The treatment must not be in place of emergency treatment of hyperkalaemia; AND<br>Patient must be undergoing treatment with a renin angiotensin aldosterone system inhibitor; OR<br>Patient must be indicated for treatment with a renin angiotensin aldosterone system inhibitor, but unable to tolerate this due to prior occurrence of hyperkalaemia.<br>Must be treated by a specialist medical practitioner with experience in the diagnosis and management of chronic kidney disease. | Compliance with Authority Required procedures |

**[73] Schedule 4, Part 1, entry for Pembrolizumab**

*insert in numerical order after existing text:*

| | | | | | |
|---|---|---|---|---|---|
| | C14324 | | | Recurrent, unresectable or metastatic triple negative breast cancer<br>The condition must have been (up until this drug therapy) untreated in the unresectable/metastatic disease stage; AND<br>The condition must have been (up until this drug therapy) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy in breast cancer; AND<br>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND<br>The treatment must be in combination with chemotherapy; AND<br>The condition must have both: (i) programmed cell death ligand 1 (PD-L1) expression confirmed by a validated test, (ii) a Combined Positive Score (CPS) of at least 10 at treatment initiation.<br>Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR<br>Patient must be undergoing continuing treatment with this drug - both the following are true: (i) the condition has not progressed on active treatment with this drug, (ii) this prescription does not extend PBS subsidy beyond 24 cumulative months from the first administered dose; AND<br>Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR<br>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions. | Compliance with Authority Required procedures - Streamlined Authority Code 14324 |

**[74] Schedule 4, Part 1, omit entry for Polyvinyl alcohol**

**[75] Schedule 4, Part 1, omit entry for Saquinavir**

**[76] Schedule 4, Part 1, entry for Tofacitinib**

**(a)** *omit:*

| | | | | | |
|---|---|---|---|---|---|
| | C14207 | P14207 | | Ankylosing spondylitis<br>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements<br>The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND<br>Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2023; AND<br>Patient must have had at least 2 of the following prior to commencing non-PBS-subsidised treatment: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND<br>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<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 16 weeks of treatment under this restriction.<br>Patient must be at least 18 years of age.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.<br>The application must include details of the NSAIDs trialled, their doses and duration of treatment. | Compliance with Written Authority Required procedures |

| | | | | | |
|---|---|---|---|---|---|
| | | | | If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.<br>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.<br>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.<br>The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition:<br>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and<br>(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.<br>The baseline BASDAI score and ESR or CRP level must have been determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. If the above requirement to demonstrate an elevated ESR or CRP could not be met, the application must state the reason this criterion could not be satisfied.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following:<br>(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and<br>(ii) a baseline BASDAI score; and<br>(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and<br>(iv) baseline ESR and/or CRP level<br>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:<br>(a) an ESR measurement no greater than 25 mm per hour; or<br>(b) a CRP measurement no greater than 10 mg per L; or<br>(c) an ESR or CRP measurement reduced by at least 20% from baseline.<br>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.<br>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |

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

| | | | | | |
|---|---|---|---|---|---|
| | C14345 | P14345 | | Ankylosing spondylitis<br>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements<br>The condition must be radiographically (plain X-ray) confirmed Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; AND | Compliance with Written Authority Required procedures |

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| | | | | Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2023; AND<br>Patient must have had at least 2 of the following prior to commencing non-PBS-subsidised treatment: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; or (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); or (iii) limitation of chest expansion relative to normal values for age and gender; AND<br>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 prior to commencing non-PBS-subsidised treatment; AND<br>Patient must have demonstrated an adequate response to treatment with this drug; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction.<br>Patient must be at least 18 years of age.<br>Must be treated by a rheumatologist; OR<br>Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.<br>The application must include details of the NSAIDs trialled, their doses and duration of treatment.<br>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.<br>If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.<br>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.<br>The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition:<br>(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and<br>(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.<br>The baseline BASDAI score and ESR or CRP level must have been determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. If the above requirement to demonstrate an elevated ESR or CRP could not be met, the application must state the reason this criterion could not be satisfied.<br>The authority application must be made in writing and must include:<br>(a) a completed authority prescription form; and<br>(b) a completed Ankylosing Spondylitis PBS Authority Application Form which includes the following:<br>(i) details of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and<br>(ii) a baseline BASDAI score; and<br>(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and<br>(iv) baseline ESR and/or CRP level<br>An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:<br>(a) an ESR measurement no greater than 25 mm per hour; or<br>(b) a CRP measurement no greater than 10 mg per L; or<br>(c) an ESR or CRP measurement reduced by at least 20% from baseline.<br>Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and supplied in all subsequent continuing treatment applications.<br>An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks | |

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| | | | | of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.<br>Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.<br>If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. | |

**[77] Schedule 4, Part 1, entry for Venetoclax**

**(a)** *omit:*

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| | C11053 | | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Initial treatment in first-line therapy - Dose titration (weeks 1 to 4 of a 5-week ramp-up schedule)<br>The condition must be untreated; AND<br>Patient must be inappropriate for fludarabine based chemo-immunotherapy; AND<br>The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses); AND<br>Patient must have a creatinine clearance 30 mL/min or greater; AND<br>Patient must have a total cumulative illness rating scale (CIRS) score of greater than 6 (excluding CLL-induced illness or organ damage); OR<br>Patient must have a creatinine clearance less than 70 mL/min. | Compliance with Authority Required procedures |

**(b)** *omit:*

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| | C12482 | | | Chronic lymphocytic leukaemia (CLL)<br>Initial treatment - Dose titration<br>Patient must not have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must be considered unsuitable for treatment or retreatment with a purine analogue; AND<br>The condition must have relapsed or be refractory to at least one prior therapy; AND<br>Patient must have a WHO performance status of 0 or 1; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The treatment must be used as monotherapy for this condition under this restriction.<br>A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following:<br>a) Failure to respond (stable disease or disease progression on treatment), or a progression-free interval of less than 3 years from treatment with a purine analogue-based therapy and anti-CD20-containing chemoimmunotherapy regimen after at least two cycles;<br>b) Age is 70 years or older;<br>c) Age is 65 years or older and the presence of comorbidities (Cumulative Illness Rating Scale of 6 or greater, or creatinine clearance of less than 70 mL/min) that might place the patient at an unacceptable risk for treatment-related toxicity with purine analogue-based therapy, provided they have received one or more prior treatment including at least two cycles of an alkylating agent-based (or purine analogue-based) anti-CD20 antibody-containing chemoimmunotherapy regimen; | Compliance with Authority Required procedures |

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| | | | | d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia;<br>e) Evidence of one or more 17p chromosomal deletions demonstrated by a Medicare Benefits Schedule listed test. | |

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

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| | C14325 | | | Chronic lymphocytic leukaemia (CLL)<br>Dose titration occurring at the start of treatment for relapsed/refractory disease<br>The condition must have relapsed or be refractory to at least one prior therapy; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition; AND<br>The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition.<br>Patient must not be undergoing retreatment with this drug where prior, active treatment of CLL/SLL with this same drug was unable to prevent disease progression. | Compliance with Authority Required procedures |
| | C14340 | | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Initial treatment in first-line therapy - Dose titration (weeks 1 to 4 of a 5-week ramp-up schedule)<br>The condition must be untreated with drug treatment at the time of the first dose of this drug; OR<br>Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL; AND<br>The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND<br>The treatment must be in combination with obinutuzumab (refer to Product Information for timing of obinutuzumab and venetoclax doses). | Compliance with Authority Required procedures |

**[78] Schedule 4, Part 1, entry for Zanubrutinib**

*insert in numerical order after existing text:*

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| | C14337 | | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>First line drug treatment of this indication<br>The condition must be untreated with drug treatment at the time of the first dose of this drug; OR<br>Patient must have developed an intolerance of a severity necessitating permanent treatment withdrawal following use of another drug PBS indicated as first-line drug treatment of CLL/SLL; AND<br>The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.<br>Patient must be undergoing initial treatment with this drug - this is the first prescription for this drug; OR<br>Patient must be undergoing continuing treatment with this drug - the condition has not progressed whilst the patient has actively been on this drug. | Compliance with Authority Required procedures |
| | C14344 | | | Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)<br>Treatment of relapsed/refractory disease<br>The condition must have relapsed or be refractory to at least one prior therapy; AND<br>The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on | Compliance with Authority Required procedures |

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| | | | | CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.<br>Patient must not be undergoing retreatment with this drug where prior, active treatment of CLL/SLL with this same drug was unable to prevent disease progression; AND<br>Patient must be undergoing treatment through this treatment phase listing for the first time; OR<br>Patient must be undergoing treatment through this treatment phase listing on a subsequent occasion, with disease progression being absent. | |

**[79] Schedule 5, after entry for Aflibercept in the form Solution for intravitreal injection 4 mg in 100 microlitres (40 mg per mL)**

*insert:*

| | | | | |
|---|---|---|---|---|
| Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides | GRP-27823 | Oral powder with 2'-fucosyllactose and lacto-N-neotetraose, 400 g (Alfamino) | Oral | Alfamino |
| | | Oral powder 400 g (Alfamino) | Oral | Alfamino |

**[80] Schedule 5, entry for Amoxicillin with clavulanic acid in the form Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)**

*insert in alphabetical order in the column headed "Brand":* **Alphaclav Duo Forte Viatris**

**[81] Schedule 5, omit entry for Colestyramine**

**[82] Schedule 5, omit entry for Everolimus**

**[83] Schedule 5, after entry for Glatiramer in the form Injection containing glatiramer acetate 40 mg in 1 mL single dose pre-filled syringe**

*insert:*

| | | | | |
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| Glucagon | GRP-27816 | Injection set containing glucagon hydrochloride 1 mg (1 I.U.) and 1 mL solvent in disposable syringe | Injection | GlucaGen Hypokit |
| | | Injection set containing glucagon hydrochloride 1 mg (1 I.U.) and 1 mL solvent in disposable syringe (s19A) | Injection | GlucaGen Hypokit (Germany) |

**[84] Schedule 5, entry for Imatinib in the form Capsule 100 mg (as mesilate) *[GRP-21074]***

*omit from the column headed "Brand":* **Imatinib GH**

**[85] Schedule 5, entry for Imatinib in the form Capsule 100 mg (as mesilate) *[GRP-25645]***

*omit from the column headed "Brand":* **Imatinib GH**

**[86] Schedule 5, after entry for Morphine in the form Injection containing morphine sulfate pentahydrate 10 mg in 1 mL**

*insert:*

| | | | | |
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| Naloxone | GRP-27818 | Nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2 | Nasal | Nyxoid |
| | | Nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2 (s19A) | Nasal | Nyxoid (UK) |

**[87] Schedule 5, entry for Ondansetron**

*omit:*

| | | | | |
|---|---|---|---|---|
| | GRP-16933 | Tablet (orally disintegrating) 4 mg | Oral | APO-Ondansetron ODT<br>APX-Ondansetron ODT<br>Ondansetron AN ODT<br>Ondansetron Mylan ODT<br>Ondansetron ODT-DRLA<br>Ondansetron ODT Lupin<br>Ondansetron SZ ODT<br>Zotren ODT |
| | | Wafer 4 mg | Oral | Zofran Zydis |

**[88] Schedule 5, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg *[GRP-17042]***

*omit from the column headed "Brand":* **Ondansetron ODT Lupin**