

**PB 109 of 2021**

**National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2021   
(No. 10)**

*National Health Act 1953*

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I, NIKOLAI TSYGANOV, Assistant Secretary (Acting), Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health, 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 28 October 2021

**NIKOLAI TSYGANOV**

Assistant Secretary (Acting)

Pricing and PBS Policy Branch

Technology Assessment and Access Division

Department of Health

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1. **Name of Instrument**
2. This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2021 (No. 10)*.
3. This instrument may also be cited as PB 109 of 2021.
4. **Commencement**
5. Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

| Commencement information | | |
| --- | --- | --- |
| Column 1 | Column 2 | Column 3 |
| Provisions | Commencement | Date/Details |
| 1. *The whole of this instrument* | *1 November 2021* | *1 November 2021* |

Note: This table relates only to the provisions of this instrument as originally made.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

1. 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.
2. **Authority**

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

1. **Schedule**

Schedule 1 to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 - Amendments

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

1. Section 4 Definitions
   1. *omit:*

***prescriber code*** means any of the following codes identifying the kind of person mentioned for the code:

(a) MP—medical practitioner;

(b) PDP—participating dental practitioner;

(c) AO—authorised optometrist;

(d) MW—authorised midwife;

(e) NP—authorised nurse practitioner;

1. Schedule 1, Part 1, entry for Abatacept in the form Injection 125 mg in 1 mL single dose autoinjector *[Maximum Quantity: 4; Number of   
   Repeats: 3]*
   1. insert in numerical order in the column headed “Circumstances”: C12378 C12385
2. Schedule 1, Part 1, entry for Abatacept in the form Injection 125 mg in 1 mL single dose autoinjector *[Maximum Quantity: 4; Number of   
   Repeats: 5]*
   * 1. insert in numerical order in the column headed “Circumstances”: C12378 C12385
     2. insert in numerical order in the column headed “Purposes”: P12378 P12385
3. Schedule 1, Part 1, entry for Abatacept in the form Injection 125 mg in 1 mL single dose pre-filled syringe *[Maximum Quantity: 4; Number of Repeats: 3]*
   1. insert in numerical order in the column headed “Circumstances”: C12378 C12385
4. Schedule 1, Part 1, entry for Abatacept in the form Injection 125 mg in 1 mL single dose pre-filled syringe *[Maximum Quantity: 4; Number of Repeats: 5]*
   * 1. insert in numerical order in the column headed “Circumstances”: C12378 C12385
     2. insert in numerical order in the column headed “Purposes”: P12378 P12385
5. Schedule 1, Part 1, entry for Abemaciclib in each of the forms: Tablet 50 mg; Tablet 100 mg; and Tablet 150 mg
   1. omit from the column headed “Circumstances”: C10019 C10032 substitute: C12348 C12367 C12380
6. Schedule 1,  Part 1, entry for Abiraterone in each of the forms: Tablet containing abiraterone acetate 250 mg; and Tablet containing abiraterone acetate 500 mg
   1. omit from the column headed “Circumstances”: C12173 substitute: C12352
7. Schedule 1, Part 1, entry for Acalabrutinib
   1. omit from the column headed “Circumstances”: C10669
8. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 0]*
   1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
9. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 2]*
   1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
10. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 3]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
11. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 4]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
12. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 5]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
      2. insert in numerical order in the column headed “Purposes”: P12354 P12364 P12366 P12391
13. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Maximum Quantity: 4; Number of Repeats: 2; Pack Quantity: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
14. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Maximum Quantity: 4; Number of Repeats: 2; Pack Quantity: 4]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
15. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Maximum Quantity: 4; Number of Repeats: 5; Pack Quantity: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
16. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Maximum Quantity: 4; Number of Repeats: 5; Pack Quantity: 4]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
17. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Maximum Quantity: 6; Number of Repeats: 0; Pack Quantity: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
18. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen *[Maximum Quantity: 6; Number of Repeats: 0; Pack Quantity: 6]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
19. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
20. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
21. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 3]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
22. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 4]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
23. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 5]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
      2. insert in numerical order in the column headed “Purposes”: P12354 P12364 P12366 P12391
24. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Maximum Quantity: 6; Number of Repeats: 0; Pack Quantity: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
25. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled syringe *[Maximum Quantity: 6; Number of Repeats: 0; Pack Quantity: 6]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
26. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Amgevita;* *Maximum Quantity: 2; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
27. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hadlima;* *Maximum Quantity: 2; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
28. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hyrimoz;* *Maximum Quantity: 2; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
29. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Idacio;* *Maximum Quantity: 2; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
30. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Amgevita;* *Maximum Quantity: 2; Number of Repeats: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
31. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hadlima;* *Maximum Quantity: 2; Number of Repeats: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
32. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hyrimoz;* *Maximum Quantity: 2; Number of Repeats: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
33. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Idacio;* *Maximum Quantity: 2; Number of Repeats: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
34. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Amgevita;* *Maximum Quantity: 2; Number of Repeats: 3]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
35. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hadlima;* *Maximum Quantity: 2; Number of Repeats: 3]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
36. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hyrimoz;* *Maximum Quantity: 2; Number of Repeats: 3]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
37. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Idacio;* *Maximum Quantity: 2; Number of Repeats: 3]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
38. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Amgevita;* *Maximum Quantity: 2; Number of Repeats: 4]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
39. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hadlima;* *Maximum Quantity: 2; Number of Repeats: 4]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
40. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hyrimoz;* *Maximum Quantity: 2; Number of Repeats: 4]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
41. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Idacio;* *Maximum Quantity: 2; Number of Repeats: 4]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
42. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Amgevita;* *Maximum Quantity: 2; Number of Repeats: 5;* *Section 100/ Prescriber Bag only code: Nil]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
      2. insert in numerical order in the column headed “Purposes”: P12354 P12364 P12366 P12391
43. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hadlima;* *Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only code: Nil]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
      2. insert in numerical order in the column headed “Purposes”: P12354 P12364 P12366 P12391
44. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hyrimoz;* *Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only code: Nil]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
      2. insert in numerical order in the column headed “Purposes”: P12354 P12364 P12366 P12391
45. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Idacio;* *Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only code: Nil]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
      2. insert in numerical order in the column headed “Purposes”: P12354 P12364 P12366 P12391
46. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Amgevita; Maximum Quantity: 4; Number of Repeats: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
47. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hadlima;* *Maximum Quantity: 4; Number of Repeats: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
48. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hyrimoz;* *Maximum Quantity: 4; Number of Repeats: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
49. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Idacio;* *Maximum Quantity: 4; Number of Repeats: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
50. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Amgevita;* *Maximum Quantity: 4; Number of Repeats: 5]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
51. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hadlima;* *Maximum Quantity: 4; Number of Repeats: 5]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
52. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hyrimoz;* *Maximum Quantity: 4; Number of Repeats: 5]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
53. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Idacio;* *Maximum Quantity: 4; Number of Repeats: 5]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
54. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Amgevita;* *Maximum Quantity: 6; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
55. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hadlima;* *Maximum Quantity: 6; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
56. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Hyrimoz;* *Maximum Quantity: 6; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
57. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled pen *[Brand: Idacio;* *Maximum Quantity: 6; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
58. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Amgevita;* *Maximum Quantity: 2; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
59. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Hadlima;* *Maximum Quantity: 2; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
60. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Hyrimoz;* *Maximum Quantity: 2; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
61. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Idacio;* *Maximum Quantity: 2; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
62. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Amgevita;* *Maximum Quantity: 2; Number of Repeats: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
63. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Hadlima;* *Maximum Quantity: 2; Number of Repeats: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
64. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Hyrimoz;* *Maximum Quantity: 2; Number of Repeats: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
65. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Idacio;* *Maximum Quantity: 2; Number of Repeats: 2]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
66. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Amgevita;* *Maximum Quantity: 2; Number of Repeats: 3]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
67. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Hadlima;* *Maximum Quantity: 2; Number of Repeats: 3]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
68. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Hyrimoz;* *Maximum Quantity: 2; Number of Repeats: 3]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
69. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Idacio;* *Maximum Quantity: 2; Number of Repeats: 3]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
70. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Amgevita;* *Maximum Quantity: 2; Number of Repeats: 4]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
71. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Hadlima;* *Maximum Quantity: 2; Number of Repeats: 4]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
72. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Hyrimoz;* *Maximum Quantity: 2; Number of Repeats: 4]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
73. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Idacio;* *Maximum Quantity: 2; Number of Repeats: 4]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
74. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Amgevita;* *Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only code: Nil]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
      2. insert in numerical order in the column headed “Purposes”: P12354 P12364 P12366 P12391
75. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Hadlima;* *Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only code: Nil]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
      2. insert in numerical order in the column headed “Purposes”: P12354 P12364 P12366 P12391
76. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Hyrimoz;* *Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only code: Nil]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
      2. insert in numerical order in the column headed “Purposes”: P12354 P12364 P12366 P12391
77. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Idacio;* *Maximum Quantity: 2; Number of Repeats: 5; Section 100/ Prescriber Bag only code: Nil]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
      2. insert in numerical order in the column headed “Purposes”: P12354 P12364 P12366 P12391
78. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Amgevita;* *Maximum Quantity: 6; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
79. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Hadlima;* *Maximum Quantity: 6; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
80. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Hyrimoz;* *Maximum Quantity: 6; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
81. Schedule 1, Part 1, entry for Adalimumab in the form Injection 40 mg in 0.8 mL pre-filled syringe *[Brand: Idacio;* *Maximum Quantity: 6; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12364 C12366 C12391
82. Schedule 1, Part 1, entry for Aprepitant
    * 1. insert in the column headed “Schedule Equivalent” for the existing brand: **a**
      2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | APREPITANT SCP | XC | MP NP | C4211 C4215 C6370 C6444 |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C4216 C4223 C6383 C6464 |  | 1 | 5 | 1 |  | C(100) |

1. Schedule 1, Part 1, entry for Azacitidine
   * 1. omit from the column headed “Responsible Person” for the brand “Celazadine”: JU substitute: **CJ**
     2. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Vidaza | CJ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Azathioprine in the form Tablet 50 mg
   1. omit from the column headed “Responsible Person” for the brand “Imazan”: ER substitute: ZS
2. Schedule 1, Part 1, entry for Baricitinib in the form Tablet 2 mg *[Maximum Quantity: 28; Number of Repeats: 3]*
   1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
3. Schedule 1, Part 1, entry for Baricitinib in the form Tablet 2 mg *[Maximum Quantity: 28; Number of Repeats: 5]*
   * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
     2. insert in numerical order in the column headed “Purposes”: P12354 P12366
4. Schedule 1, Part 1, entry for Baricitinib in the form Tablet 4 mg *[Maximum Quantity: 28; Number of Repeats: 3]*
   1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
5. Schedule 1, Part 1, entry for Baricitinib in the form Tablet 4 mg *[Maximum Quantity: 28; Number of Repeats: 5]*
   * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
     2. insert in numerical order in the column headed “Purposes”: P12354 P12366
6. Schedule 1, Part 1, entry for Beclometasone with formoterol and glycopyrronium
   1. omit from the column headed “Circumstances”: C10167 substitute: C12349
7. Schedule 1, Part 1, entry for Bicalutamide
   1. omit from the column headed “Responsible Person” for the brand “Bicalox”: ER substitute: ZS
8. Schedule 1, Part 1, entry for Bivalirudin
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Angiomax | XM | MP | C4919 |  | 1 | 0 | 1 |  |  |

* + 1. omit from the column headed “Schedule Equivalent” for the brand “Bivalirudin APOTEX”: **a**

1. Schedule 1, Part 1, after entry for Bortezomib in the form Powder for injection 1 mg
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Powder for injection 2.5 mg | Injection |  | Bortezomib Juno | JU | MP | C11099 |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, Part 1, entry for Botulinum toxin type A purified neurotoxin complex
   1. omit from the column headed “Circumstances”: C10298
2. Schedule 1, Part 1, after entry for Budesonide with formoterol in the form Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Budesonide with glycopyrronium and formoterol | Pressurised inhalation containing budesonide  160 micrograms with glycopyrronium 7.2 micrograms and formoterol fumarate dihydrate 5 micrograms per dose, 120 doses | Inhalation by mouth |  | Breztri Aerosphere | AP | MP NP | C12349 |  | 1 | 5 | 1 |  |  |

1. Schedule 1, Part 1, entry for Calcipotriol with betamethasone
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Gel containing calcipotriol 50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g | Application |  | Daivobet 50/500 gel | LO | MP NP | C7947 |  | 1 | 1 | 1 |  |  |

1. Schedule 1, Part 1, entry for Calcitriol
   1. omit from the column headed “Responsible Person” for the brand “Calciprox”: ER substitute: ZS
2. Schedule 1, Part 1, entry for Carvedilol in the form Tablet 3.125 mg
   1. omit from the column headed “Responsible Person” for the brand “Volirop 3.125”: DO substitute: ZS
3. Schedule 1, Part 1, entry for Carvedilol in the form Tablet 6.25 mg
   1. omit from the column headed “Responsible Person” for the brand “Volirop 6.25”: DO substitute: ZS
4. Schedule 1, Part 1, entry for Carvedilol in the form Tablet 12.5 mg
   1. omit from the column headed “Responsible Person” for the brand “Volirop 12.5”: DO substitute: ZS
5. Schedule 1, Part 1, entry for Carvedilol in the form Tablet 25 mg
   1. omit from the column headed “Responsible Person” for the brand “Volirop 25”: DO substitute: ZS
6. Schedule 1, Part 1, entry for Certolizumab pegol
   1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Certolizumab pegol | Injection 200 mg in 1 mL single use pre-filled syringe | Injection |  | Cimzia | UC | MP | C8626 C8627 C8679 C8706 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10459 C10513 C11386 C11430 C11686 C11748 C12354 C12366 C12392 C12393 | P10459 P12392 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C8626 C8627 C8679 C8706 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10459 C10513 C11386 C11430 C11686 C11748 C12354 C12366 C12392 C12393 | P8706 P9185 P9625 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C8626 C8627 C8679 C8706 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10459 C10513 C11386 C11430 C11686 C11748 C12354 C12366 C12392 C12393 | P12393 | 2 | 4 | 2 |  |  |
|  |  |  |  |  |  | MP | C8626 C8627 C8679 C8706 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10459 C10513 C11386 C11430 C11686 C11748 C12354 C12366 C12392 C12393 | P8627 P8679 P9063 P9105 P9430 P9431 P10431 P12366 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C8626 C8627 C8679 C8706 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10459 C10513 C11386 C11430 C11686 C11748 C12354 C12366 C12392 C12393 | P8626 P9073 P9074 P9183 P9442 P9537 P9610 P10513 P11386 P11430 P11686 P11748 P12354 | 6 | 0 | 2 |  |  |
|  | Solution for injection 200 mg in  1 mL pre-filled pen | Injection |  | Cimzia | UC | MP | C8626 C8627 C8679 C8706 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10459 C10513 C11386 C11430 C11686 C11748 C12354 C12366 C12392 C12393 | P10459 P12392 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C8626 C8627 C8679 C8706 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10459 C10513 C11386 C11430 C11686 C11748 C12354 C12366 C12392 C12393 | P8706 P9185 P9625 | 2 | 2 | 2 |  |  |
|  |  |  |  |  |  | MP | C8626 C8627 C8679 C8706 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10459 C10513 C11386 C11430 C11686 C11748 C12354 C12366 C12392 C12393 | P12393 | 2 | 4 | 2 |  |  |
|  |  |  |  |  |  | MP | C8626 C8627 C8679 C8706 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10459 C10513 C11386 C11430 C11686 C11748 C12354 C12366 C12392 C12393 | P8627 P8679 P9063 P9105 P9430 P9431 P10431 P12366 | 2 | 5 | 2 |  |  |
|  |  |  |  |  |  | MP | C8626 C8627 C8679 C8706 C9063 C9073 C9074 C9105 C9183 C9185 C9430 C9431 C9442 C9537 C9610 C9625 C10431 C10459 C10513 C11386 C11430 C11686 C11748 C12354 C12366 C12392 C12393 | P8626 P9073 P9074 P9183 P9442 P9537 P9610 P10513 P11386 P11430 P11686 P11748 P12354 | 6 | 0 | 2 |  |  |

1. Schedule 1, Part 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 100 mg
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | Cyprostat-100 | SY | MP |  |  | 50 | 5 | 50 |  |  |

1. Schedule 1, Part 1, entry for Daratumumab in each of the forms: Solution concentrate for I.V. infusion 100 mg in 5 mL; and Solution concentrate for I.V. infusion 400 mg in 20 mL
   * 1. omit from the column headed “Circumstances”: C11142
     2. insert in numerical order in the column headed “Circumstances”: C12350
     3. omit from the column headed “Section 100/ Prescriber Bag only”: D(100) substitute: PB(100)
2. Schedule 1, Part 1, after entry for Daratumumab in the form Solution concentrate for I.V. infusion 400 mg in 20 mL
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Solution for subcutaneous injection containing daratumumab 1800 mg in 15 mL | Injection |  | Darzalex | JC | MP | C11075 C11076 C12350 C12369 | P11076 | 1 | 4 | 1 |  |  |
|  |  |  |  |  |  | MP | C11075 C11076 C12350 C12369 | P11075 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C11075 C11076 C12350 C12369 | P12369 | 1 | 7 | 1 |  |  |
|  |  |  |  |  |  | MP | C11075 C11076 C12350 C12369 | P12350 | 1 | 8 | 1 |  |  |

1. Schedule 1, Part 1, after entry for Darbepoetin alfa in the form Injection 150 micrograms in 0.3 mL pre-filled syringe
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Darolutamide | Tablet 300 mg | Oral |  | Nubeqa | BN | MP | C12398 |  | 112 | 5 | 112 |  |  |

1. Schedule 1, Part 1, entry for Electrolyte replacement, oral

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Electrolyte replacement, oral | Oral rehydration salts containing glucose monohydrate 3.56 g, sodium chloride 470 mg, potassium chloride 300 mg and sodium acid citrate 530 mg per sachet, 10 | Oral |  | O.R.S. | AF | MP NP | C5889 |  | 1 | 0 | 1 |  |  |
|  |  |  | restore O.R.S. | EA | MP | C6786 |  | 30 | 0 | 1 |  |  |

1. Schedule 1, Part 1, entry for Entrectinib
   1. omit from the column headed “Circumstances”: C10672
2. Schedule 1, Part 1, entry for Enzalutamide
   1. omit from the column headed “Circumstances”: C12216 substitute: C12371
3. Schedule 1, Part 1, entry for Escitalopram in each of the forms: Tablet 10 mg (as oxalate); and Tablet 20 mg (as oxalate)
   1. omit from the column headed “Responsible Person” for the brand “Cilopam-S”: ER substitute: ZS
4. Schedule 1, Part 1, entry for Etanercept in the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent   
   1 mL *[Maximum Quantity: 2; Number of Repeats: 3]*
   1. insert in numerical order in the column headed “Circumstances”: C12354 C12359 C12366 C12389
5. Schedule 1, Part 1, entry for Etanercept in the form Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent   
   1 mL *[Maximum Quantity: 2; Number of Repeats: 5]*
   * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12359 C12366 C12389
     2. insert in numerical order in the column headed “Purposes”: P12354 P12359 P12366 P12389
6. Schedule 1, Part 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 *[Brand: Brenzys;* *Maximum Quantity: 1; Number of Repeats: 3]*
   1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
7. Schedule 1, Part 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 *[Brand: Enbrel;* *Maximum Quantity: 1; Number of Repeats: 3]*
   1. insert in numerical order in the column headed “Circumstances”: C12354 C12359 C12366 C12389
8. Schedule 1, Part 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 *[Brand: Brenzys;* *Maximum Quantity: 1; Number of Repeats: 5]*
   * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
     2. insert in numerical order in the column headed “Purposes”: P12354 P12366
9. Schedule 1, Part 1, entry for Etanercept in the form Injection 50 mg in 1 mL single use auto-injector, 4 *[Brand: Enbrel;* *Maximum Quantity: 1; Number of Repeats: 5]*
   * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12359 C12366 C12389
     2. insert in numerical order in the column headed “Purposes”: P12354 P12359 P12366 P12389
10. Schedule 1, Part 1, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 *[Brand: Brenzys; Maximum Quantity: 1; Number of Repeats: 3]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
11. Schedule 1, Part 1, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 *[Brand: Enbrel; Maximum   
    Quantity: 1; Number of Repeats: 3]*
    1. insert in numerical order in the column headed “Circumstances”: C12354 C12359 C12366 C12389
12. Schedule 1, Part 1, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 *[Brand: Brenzys; Maximum Quantity: 1; Number of Repeats: 5]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
      2. insert in numerical order in the column headed “Purposes”: P12354 P12366
13. Schedule 1, Part 1, entry for Etanercept in the form Injections 50 mg in 1 mL single use pre-filled syringes, 4 *[Brand: Enbrel; Maximum   
    Quantity: 1; Number of Repeats: 5]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12359 C12366 C12389
      2. insert in numerical order in the column headed “Purposes”: P12354 P12359 P12366 P12389
14. Schedule 1, Part 1, entry for Evolocumab in the form Injection 140 mg in 1 mL single use pre-filled pen *[Maximum Quantity: 2; Number of Repeats: 5]*
    * 1. omit from the column headed “Circumstances”: C10358 C10370
      2. omit from the column headed “Circumstances”: C10389
      3. omit from the column headed “Purposes”: P10358 P10389
15. Schedule 1, Part 1, entry for Evolocumab in the form Injection 140 mg in 1 mL single use pre-filled pen *[Maximum Quantity: 3; Number of Repeats: 5]*
    * 1. omit from the column headed “Circumstances”: C10358 C10370
      2. omit from the column headed “Circumstances”: C10389
      3. omit from the column headed “Purposes”: P10370
16. Schedule 1, Part 1, entry for Evolocumab in the form Injection 420 mg in 3.5 mL single use pre-filled cartridge
    * 1. omit from the column headed “Circumstances”: C10358 C10370
      2. omit from the column headed “Circumstances”: C10389
17. Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-10 mg
    1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | EZESIM 10/10 | RZ | MP NP | C7958 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-20 mg
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | EZESIM 10/20 | RZ | MP NP | C7958 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-40 mg
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | EZESIM 10/40 | RZ | MP NP | C7957 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Ezetimibe with simvastatin in the form Tablet 10 mg-80 mg
   1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | a | EZESIM 10/80 | RZ | MP NP | C7957 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Fluticasone furoate with umeclidinium and vilanterol
   1. omit from the column headed “Circumstances”: C10167 substitute: C12349
2. Schedule 1, Part 1, entry for Furosemide in the form Tablet 40 mg
   1. omit from the column headed “Responsible Person” for the brand “Frusax”: ER substitute: ZS
3. Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 3]*
   1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
4. Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled pen *[Maximum Quantity: 1; Number of Repeats: 5]*
   * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
     2. insert in numerical order in the column headed “Purposes”: P12354 P12366
5. Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 3]*
   1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
6. Schedule 1, Part 1, entry for Golimumab in the form Injection 50 mg in 0.5 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 5]*
   * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
     2. insert in numerical order in the column headed “Purposes”: P12354 P12366
7. Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) *[Brand: Imatinib-APOTEX;* *Maximum Quantity: 60; Number of Repeats: 2]*
   * 1. insert in numerical order in the column headed “Circumstances”: C9238
     2. insert in numerical order in the column headed “Circumstances”: C9278
8. Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) *[Brand: IMATINIB-DRLA;* *Maximum Quantity: 60; Number of Repeats: 2]*
   * 1. insert in numerical order in the column headed “Circumstances”: C9208
     2. insert in numerical order in the column headed “Circumstances”: C9238
     3. insert in numerical order in the column headed “Circumstances”: C9278
     4. insert in numerical order in the column headed “Circumstances”: C9319
     5. insert in numerical order in the column headed “Purposes”: P9208 P9319
9. Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) *[Brand: Imatinib-APOTEX;* *Maximum Quantity: 60; Number of Repeats: 5]*
   * 1. insert in numerical order in the column headed “Circumstances”: C9238
     2. insert in numerical order in the column headed “Circumstances”: C9278
     3. insert in numerical order in the column headed “Purposes”: P9238
     4. insert in numerical order in the column headed “Purposes”: P9278
10. Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) *[Brand:* *IMATINIB-DRLA; Maximum Quantity: 60; Number of Repeats: 5]*
    * 1. insert in numerical order in the column headed “Circumstances”: C9208
      2. insert in numerical order in the column headed “Circumstances”: C9238
      3. insert in numerical order in the column headed “Circumstances”: C9278
      4. insert in numerical order in the column headed “Circumstances”: C9319
      5. insert in numerical order in the column headed “Purposes”: P9238
      6. insert in numerical order in the column headed “Purposes”: P9278
11. Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) *[Brand: Imatinib-APOTEX;* *Maximum Quantity: 30; Number of Repeats: 2]*
    * 1. insert in numerical order in the column headed “Circumstances”: C9238
      2. insert in numerical order in the column headed “Circumstances”: C9278
12. Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) *[Brand:* *IMATINIB-DRLA;Maximum Quantity: 30; Number of Repeats: 2]*
    * 1. insert in numerical order in the column headed “Circumstances”: C9208
      2. insert in numerical order in the column headed “Circumstances”: C9238
      3. insert in numerical order in the column headed “Circumstances”: C9278
      4. insert in numerical order in the column headed “Circumstances”: C9319
      5. insert in numerical order in the column headed “Purposes”: P9208 P9319
13. Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) *[Brand: Imatinib-APOTEX;* *Maximum Quantity: 30; Number of Repeats: 5]*
    * 1. insert in numerical order in the column headed “Circumstances”: C9238
      2. insert in numerical order in the column headed “Circumstances”: C9278
      3. insert in numerical order in the column headed “Purposes”: P9238
      4. insert in numerical order in the column headed “Purposes”: P9278
14. Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) *[Brand: IMATINIB-DRLA; Maximum Quantity: 30; Number of Repeats: 5]*
    * 1. insert in numerical order in the column headed “Circumstances”: C9208
      2. insert in numerical order in the column headed “Circumstances”: C9238
      3. insert in numerical order in the column headed “Circumstances”: C9278
      4. insert in numerical order in the column headed “Circumstances”: C9319
      5. insert in numerical order in the column headed “Purposes”: P9238
      6. insert in numerical order in the column headed “Purposes”: P9278
15. Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate) *[Brand: Gilmat;* *Maximum Quantity: 60; Number of Repeats: 2]*
    * 1. insert in numerical order in the column headed “Circumstances”: C9208
      2. insert in numerical order in the column headed “Circumstances”: C9238
      3. insert in numerical order in the column headed “Circumstances”: C9278
      4. insert in numerical order in the column headed “Circumstances”: C9319
      5. insert in numerical order in the column headed “Purposes”: P9208 P9319
16. Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate) *[Brand: Imatinib-Teva; Maximum Quantity: 60; Number of   
    Repeats: 2]*
    * 1. insert in numerical order in the column headed “Circumstances”: C9204 C9206
      2. insert in numerical order in the column headed “Circumstances”: C9208
      3. insert in numerical order in the column headed “Circumstances”: C9238
      4. insert in numerical order in the column headed “Circumstances”: C9278
      5. insert in numerical order in the column headed “Circumstances”: C9319
      6. insert in numerical order in the column headed “Purposes”: P9208 P9319
17. Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate) *[Brand: Gilmat;* *Maximum Quantity: 60; Number of Repeats: 5]*
    * 1. insert in numerical order in the column headed “Circumstances”: C9208
      2. insert in numerical order in the column headed “Circumstances”: C9238
      3. insert in numerical order in the column headed “Circumstances”: C9278
      4. insert in numerical order in the column headed “Circumstances”: C9319
      5. insert in numerical order in the column headed “Purposes”: P9238
      6. insert in numerical order in the column headed “Purposes”: P9278
18. Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate) *[Brand: Imatinib-Teva; Maximum Quantity: 60; Number of   
    Repeats: 5]*
    * 1. insert in numerical order in the column headed “Circumstances”: C9204 C9206
      2. insert in numerical order in the column headed “Circumstances”: C9208
      3. insert in numerical order in the column headed “Circumstances”: C9238
      4. insert in numerical order in the column headed “Circumstances”: C9278
      5. insert in numerical order in the column headed “Circumstances”: C9319
      6. insert in numerical order in the column headed “Purposes”: P9204 P9206
      7. insert in numerical order in the column headed “Purposes”: P9238
      8. insert in numerical order in the column headed “Purposes”: P9278
19. Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) *[Brand: Gilmat;* *Maximum Quantity: 30; Number of Repeats: 2]*
    * 1. insert in numerical order in the column headed “Circumstances”: C9208
      2. insert in numerical order in the column headed “Circumstances”: C9238
      3. insert in numerical order in the column headed “Circumstances”: C9278
      4. insert in numerical order in the column headed “Circumstances”: C9319
      5. insert in numerical order in the column headed “Purposes”: P9208 P9319
20. Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) *[Brand: Imatinib-Teva; Maximum Quantity: 30; Number of   
    Repeats: 2]*
    * 1. insert in numerical order in the column headed “Circumstances”: C9204 C9206
      2. insert in numerical order in the column headed “Circumstances”: C9208
      3. insert in numerical order in the column headed “Circumstances”: C9238
      4. insert in numerical order in the column headed “Circumstances”: C9278
      5. insert in numerical order in the column headed “Circumstances”: C9319
      6. insert in numerical order in the column headed “Purposes”: P9208 P9319
21. Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) *[Brand: Gilmat;* *Maximum Quantity: 30; Number of Repeats: 5]*
    * 1. insert in numerical order in the column headed “Circumstances”: C9208
      2. insert in numerical order in the column headed “Circumstances”: C9238
      3. insert in numerical order in the column headed “Circumstances”: C9278
      4. insert in numerical order in the column headed “Circumstances”: C9319
      5. insert in numerical order in the column headed “Purposes”: P9238
      6. insert in numerical order in the column headed “Purposes”: P9278
22. Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) *[Brand: Imatinib-Teva; Maximum Quantity: 30; Number of   
    Repeats: 5]*
    * 1. insert in numerical order in the column headed “Circumstances”: C9204 C9206
      2. insert in numerical order in the column headed “Circumstances”: C9208
      3. insert in numerical order on the column headed “Circumstances”: C9238
      4. insert in numerical order in the column headed “Circumstances”: C9278
      5. insert in numerical order in the column headed “Circumstances”:  C9319
      6. insert in numerical order in the column headed “Purposes”: P9204 P9206
      7. insert in numerical order in the column headed “Purposes”: P9238
      8. insert in numerical order in the column headed “Purposes”: P9278
23. Schedule 1, Part 1, entry for IncobotulinumtoxinA
    1. omit from the column headed “Circumstances”: C10594
24. Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled pen *[Maximum Quantity: 1; Number of   
    Repeats: 0]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12363 C12378 C12390
      2. insert in numerical order in the column headed “Purposes”: P12363
25. Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled pen *[Maximum Quantity: 2; Number of   
    Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12363 C12378 C12390
26. Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled pen *[Maximum Quantity: 2; Number of   
    Repeats: 2]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12363 C12378 C12390
      2. insert in numerical order in the column headed “Purposes”: P12390
27. Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled pen *[Maximum Quantity: 2; Number of   
    Repeats: 5]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12363 C12378 C12390
      2. insert in numerical order in the column headed “Purposes”: P12378
28. Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 0]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12363 C12378 C12390
      2. insert in numerical order in the column headed “Purposes”: P12363
29. Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 0]*
    1. insert in numerical order in the column headed “Circumstances”: C12363 C12378 C12390
30. Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 2]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12363 C12378 C12390
      2. insert in numerical order in the column headed “Purposes”: P12390
31. Schedule 1, Part 1, entry for Infliximab in the form Solution for injection 120 mg in 1 mL pre-filled syringe *[Maximum Quantity: 2; Number of Repeats: 5]*
    * 1. insert in numerical order in the column headed “Circumstances”: C12363 C12378 C12390
      2. insert in numerical order in the column headed “Purposes”: P12378
32. Schedule 1, Part 1, entry for Interferon gamma-1b
    1. omit from the column headed “Responsible Person” for the brand “Imukin”: EU substitute: LM
33. Schedule 1, Part 1, entry for Isotretinoin in each of the forms: Capsule 10 mg; and Capsule 20 mg
    1. omit from the column headed “Responsible Person” for the brand “Dermatane”: ER substitute: ZS
34. Schedule 1, Part 1, entry for Isotretinoin in the form Capsule 40 mg
    1. omit from the column headed “Responsible Person” for the brand “Dermatane”: ER substitute: ZS
35. Schedule 1, Part 1, entry for Lamotrigine in the form Tablet 25 mg
    1. omit from the column headed “Responsible Person” for the brand “Reedos 25”: DO substitute: ZS
36. Schedule 1, Part 1, entry for Lamotrigine in the form Tablet 50 mg
    1. omit from the column headed “Responsible Person” for the brand “Reedos 50”: DO substitute: ZS
37. Schedule 1, Part 1, entry for Lamotrigine in the form Tablet 100 mg
    1. omit from the column headed “Responsible Person” for the brand “Reedos 100”: DO substitute: ZS
38. Schedule 1, Part 1, entry for Lamotrigine in the form Tablet 200 mg
    1. omit from the column headed “Responsible Person” for the brand “Reedos 200”: DO substitute: ZS
39. Schedule 1, Part 1, entry for Letrozole
    1. omit from the column headed “Responsible Person” for the brand “Gynotril”: ER substitute: ZS
40. Schedule 1, Part 1, entry for Leuprorelin in the form I.M. injection (3 month modified release), powder for injection containing leuprorelin acetate 30 mg with diluent in pre-filled dual-chamber syringe
    * 1. omit from the column headed “Circumstances”: C6422
      2. omit from the column headed “Circumstances”: C6426
      3. insert in numerical order in the column headed “Circumstances”: C12351
41. Schedule 1, Part 1, entry for Levetiracetam in the form Oral solution 100 mg per mL, 300 mL
    1. omit from the column headed “Responsible Person” for the brand “Kerron”: DO substitute: ZS
42. Schedule 1, Part 1, entry for Levetiracetam in each of the forms: Tablet 250 mg; Tablet 500 mg; and Tablet 1 g
    1. omit from the column headed “Responsible Person” for the brand “Levactam”: ER substitute: ZS
43. Schedule 1, Part 1, entry for Lorlatinib in each of the forms: Tablet 25 mg; and Tablet 100 mg
    1. omit from the column headed “Circumstances”: C10563
44. Schedule 1, Part 1, entry for Metformin in the form Tablet containing metformin hydrochloride 500 mg
    1. omit from the column headed “Responsible Person” for the brand “Glucobete 500”: DO substitute: ZS
45. Schedule 1, Part 1, entry for Metformin in the form Tablet containing metformin hydrochloride 850 mg
    1. omit from the column headed “Responsible Person” for the brand “Glucobete 850”: DO substitute: ZS
46. Schedule 1, Part 1, entry for Metformin in the form Tablet containing metformin hydrochloride 1 g
    1. omit from the column headed “Responsible Person” for the brand “Glucobete 1000”: DO substitute: ZS
47. Schedule 1, Part 1, entry for Metoprolol in each of the forms: Tablet containing metoprolol tartrate 50 mg; and Tablet containing metoprolol tartrate 100 mg
    1. omit from the column headed “Responsible Person” for the brand “Mistrom”: ER substitute: ZS
48. Schedule 1, Part 1, entry for Nitrazepam
    1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nitrazepam | Tablet 5 mg | Oral | a | Alodorm | AF | MP NP PDP |  |  | 25 | 0 | 25 |  |  |
|  |  |  | a | Mogadon | IL | MP NP PDP |  |  | 25 | 0 | 25 |  |  |
|  |  |  | a | Alodorm | AF | MP NP |  | P6175 | 50 CN6175 | 3 CN6175 | 25 |  |  |
|  |  |  | a | Mogadon | IL | MP NP |  | P6175 | 50 CN6175 | 3 CN6175 | 25 |  |  |
|  |  |  | a | Alodorm | AF | MP NP |  | P5661 P5771 P5941 P5950 | 50 CN5661 CN5771 CN5941 CN5950 | 5 CN5661 CN5771 CN5941 CN5950 | 25 |  |  |
|  |  |  | a | Mogadon | IL | MP NP |  | P5661 P5771 P5941 P5950 | 50 CN5661 CN5771 CN5941 CN5950 | 5 CN5661 CN5771 CN5941 CN5950 | 25 |  |  |

1. Schedule 1, Part 1, entry for Olanzapine in the form Tablet 2.5 mg
   1. omit from the column headed “Responsible Person” for the brand “Ozin 2.5”: DO substitute: ZS
2. Schedule 1, Part 1, entry for Olanzapine in the form Tablet 5 mg
   1. omit from the column headed “Responsible Person” for the brand “Ozin 5”: DO substitute: ZS
3. Schedule 1, Part 1, entry for Olanzapine in the form Tablet 7.5 mg
   1. omit from the column headed “Responsible Person” for the brand “Ozin 7.5”: DO substitute: ZS
4. Schedule 1, Part 1, entry for Olanzapine in the form Tablet 10 mg
   1. omit from the column headed “Responsible Person” for the brand “Ozin 10”: DO substitute: ZS
5. Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 20 mg (as sodium sesquihydrate)
   1. omit from the column headed “Responsible Person” for the brand “Panthron”: ER substitute: ZS
6. Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Maximum Quantity: 30; Number of Repeats: 1]*
   1. omit from the column headed “Responsible Person” for the brand “Panthron”: ER substitute: ZS
7. Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Maximum Quantity: 30; Number of Repeats: 5]*
   1. omit from the column headed “Responsible Person” for the brand “Panthron”: ER substitute: ZS
8. Schedule 1, Part 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate) *[Maximum Quantity: 60; Number of Repeats: 5]*
   1. omit from the column headed “Responsible Person” for the brand “Panthron”: ER substitute: ZS
9. Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 2.5 mg
   1. omit from the column headed “Responsible Person” for the brand “PREXUM 2.5”: RW substitute: RX
10. Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 5 mg
    1. omit from the column headed “Responsible Person” for the brand “PREXUM 5”: RW substitute: RX
11. Schedule 1, Part 1, entry for Perindopril in the form Tablet containing perindopril arginine 10 mg
    1. omit from the column headed “Responsible Person” for the brand “PREXUM 10”: RW substitute: RX
12. Schedule 1, Part 1, entry for Perindopril with amlodipine in the form Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besilate)
    1. omit from the column headed “Responsible Person” for the brand “Reaptan 5/5”: RW substitute: RX
13. Schedule 1, Part 1, entry for Perindopril with amlodipine in the form Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besilate)
    1. omit from the column headed “Responsible Person” for the brand “Reaptan 5/10”: RW substitute: RX
14. Schedule 1, Part 1, entry for Perindopril with amlodipine in the form Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besilate)
    1. omit from the column headed “Responsible Person” for the brand “Reaptan 10/5”: RW substitute: RX
15. Schedule 1, Part 1, entry for Perindopril with amlodipine in the form Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besilate)
    1. omit from the column headed “Responsible Person” for the brand “Reaptan 10/10”: RW substitute: RX
16. Schedule 1, Part 1, entry for Perindopril with indapamide in the form Tablet containing perindopril arginine 2.5 mg with indapamide hemihydrate 0.625 mg
    1. omit from the column headed “Responsible Person” for the brand “PREXUM Combi LD 2.5/0.625”: RW substitute: RX
17. Schedule 1, Part 1, entry for Perindopril with indapamide in the form Tablet containing perindopril erbumine 4 mg with indapamide hemihydrate 1.25 mg
    1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | APO-Perindopril/Indapamide | TX | MP NP | C4375 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, Part 1, entry for Perindopril with indapamide in the form Tablet containing perindopril arginine 5 mg with indapamide hemihydrate 1.25 mg
   1. omit from the column headed “Responsible Person” for the brand “Prexum Combi 5/1.25”: RW substitute: RX
2. Schedule 1, Part 1, entry for Pindolol
   1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 5 mg (USP) | Oral |  | APO-PINDOL | DZ | MP NP |  |  | 100 | 5 | 100 |  |  |

1. Schedule 1, Part 1, entry for Pioglitazone in each of the forms: Tablet 15 mg (as hydrochloride); Tablet 30 mg (as hydrochloride); and Tablet   
   45 mg (as hydrochloride)
   1. omit from the column headed “Responsible Person” for the brand “Actos”: TK substitute: EW
2. Schedule 1, Part 1, entry for Quetiapine in the form Tablet 25 mg (as fumarate)
   1. omit from the column headed “Responsible Person” for the brand “Kaptan”: ER substitute: ZS
3. Schedule 1, Part 1, entry for Quetiapine in the form Tablet 100 mg (as fumarate)
   1. omit from the column headed “Responsible Person” for the brand “Kaptan”: ER substitute: ZS
4. Schedule 1, Part 1, entry for Quetiapine in the form Tablet 200 mg (as fumarate)
   1. omit from the column headed “Responsible Person” for the brand “Kaptan”: ER substitute: ZS
5. Schedule 1, Part 1, entry for Quetiapine in the form Tablet 300 mg (as fumarate)
   1. omit from the column headed “Responsible Person” for the brand “Kaptan”: ER substitute: ZS
6. Schedule 1, Part 1, entry for Raloxifene
   1. omit from the column headed “Responsible Person” for the brand “Fixta 60”: DO substitute: ZS
7. Schedule 1, Part 1, entry for Risperidone in the form Tablet 0.5 mg *[Maximum Quantity: 60; Number of Repeats: 2]*
   1. omit from the column headed “Responsible Person” for the brand “Rispernia”: ER substitute: ZS
8. Schedule 1, Part 1, entry for Risperidone in the form Tablet 0.5 mg *[Maximum Quantity: 60; Number of Repeats: 5]*
   1. omit from the column headed “Responsible Person” for the brand “Rispernia”: ER substitute: ZS
9. Schedule 1, Part 1, entry for Risperidone in the form Tablet 1 mg *[Maximum Quantity: 60; Number of Repeats: 2]*
   1. omit from the column headed “Responsible Person” for the brand “Rispernia”: ER substitute: ZS
10. Schedule 1, Part 1, entry for Risperidone in the form Tablet 1 mg *[Maximum Quantity: 60; Number of Repeats: 5]*
    1. omit from the column headed “Responsible Person” for the brand “Rispernia”: ER substitute: ZS
11. Schedule 1, Part 1, entry for Risperidone in the form Tablet 2 mg *[Maximum Quantity: 60; Number of Repeats: 2]*
    1. omit from the column headed “Responsible Person” for the brand “Rispernia”: ER substitute: ZS
12. Schedule 1, Part 1, entry for Risperidone in the form Tablet 2 mg *[Maximum Quantity: 60; Number of Repeats: 5]*
    1. omit from the column headed “Responsible Person” for the brand “Rispernia”: ER substitute: ZS
13. Schedule 1, Part 1, entry for Risperidone in the form Tablet 3 mg
    1. omit from the column headed “Responsible Person” for the brand “Rispernia”: ER substitute: ZS
14. Schedule 1, Part 1, entry for Risperidone in the form Tablet 4 mg
    1. omit from the column headed “Responsible Person” for the brand “Rispernia”: ER substitute: ZS
15. Schedule 1, Part 1, after entry for Tocilizumab in the form Concentrate for injection 80 mg in 4 mL
    1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Concentrate for injection 80 mg in 4 mL s19A | Injection |  | RoActemra | DZ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | PB(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 4 |  | PB(100) |

1. Schedule 1, Part 1, after entry for Tocilizumab in the form Concentrate for injection 200 mg in 10 mL
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Concentrate for injection  200 mg in 10 mL s19A | Injection |  | RoActemra | DZ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | PB(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 4 |  | PB(100) |

1. Schedule 1, Part 1, after entry for Tocilizumab in the form Concentrate for injection 400 mg in 20 mL
   1. insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Concentrate for injection  400 mg in 20 mL s19A | Injection |  | RoActemra | DZ | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 1 |  | PB(100) |
|  |  |  |  |  |  | MP | See Note 3 | See Note 3 | See Note 3 | See Note 3 | 4 |  | PB(100) |

1. Schedule 1, Part 1, entry for Tofacitinib in the form Tablet 5 mg *[Maximum Quantity: 56; Number of Repeats: 3]*
   1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
2. Schedule 1, Part 1, entry for Tofacitinib in the form Tablet 5 mg *[Maximum Quantity: 56; Number of Repeats: 5]*
   * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
     2. insert in numerical order in the column headed “Purposes”: P12354 P12366
3. Schedule 1, Part 1, entry for Topiramate in the form Tablet 100 mg
   1. insert in numerical order in the column headed “Circumstances” (all instances): C5325
4. Schedule 1, Part 1, entry for Trastuzumab in the form Powder for I.V. infusion 150 mg
   1. omit from the column headed “Responsible Person” for the brand “Kanjinti”: AN substitute: JU
5. Schedule 1, Part 1, entry for Trastuzumab in the form Powder for I.V. infusion 420 mg
   1. omit from the column headed “Responsible Person”: AN substitute: JU
6. Schedule 1, Part 1, entry for Triptorelin in the form Powder for I.M. injection (prolonged release) 22.5 mg (as embonate) with solvent, syringe and needles
   1. insert in the column headed “Circumstances”: C12351 C12387 C12397
7. Schedule 1, Part 1, entry for Upadacitinib in the form Tablet 15 mg *[Maximum Quantity: 28; Number of Repeats: 3]*
   1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
8. Schedule 1, entry for Upadacitinib in the form Tablet 15 mg *[Maximum Quantity: 28; Number of Repeats: 5]*
   * 1. insert in numerical order in the column headed “Circumstances”: C12354 C12366
     2. insert in numerical order in the column headed “Purposes”: P12354 P12366
9. Schedule 1, Part 1, entry for Valaciclovir in the form Tablet 500 mg (as hydrochloride)
   1. omit from the column headed “Responsible Person” for the brand “Shilova 500”: DO substitute: ZS
10. Schedule 1, Part 2, omit entry for Amino acid formula with fat, carbohydrate, vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine and supplemented with docosahexaenoic acid
11. Schedule 1, Part 2, omit entry for Bisacodyl
12. Schedule 1, Part 2, omit entry for Bortezomib
13. Schedule 1, Part 2

*insert as first entry:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Calcipotriol with betamethasone | Gel containing calcipotriol  50 micrograms with betamethasone 500 micrograms (as dipropionate) per g, 60 g | Application |  | Daivobet 50/500 gel | LO | MP NP | C7947 |  | 1 | 1 | 1 |  |  |

1. Schedule 1, Part 2, omit entry for Darunavir
2. Schedule 1, Part 2, omit entry for Diclofenac
3. Schedule 1, Part 2, omit entry for Erythromycin
4. Schedule 1, Part 2, omit entry for Grazoprevir with elbasvir
5. Schedule 1, Part 2, omit entry for High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate
6. Schedule 1, Part 2, omit entry for Indometacin
7. Schedule 1, Part 2, omit entry for Ketoconazole
8. Schedule 1, Part 2, omit entry for Macrogol 3350
9. Schedule 1, Part 2, omit entry for Metformin with glibenclamide
10. Schedule 1, Part 2, omit entry for Naproxen
11. Schedule 1, Part 2, omit entry for Nitrazepam
12. Schedule 1, Part 2, omit entry for Olaparib
13. Schedule 1, Part 2, omit entry for Phenoxybenzamine
14. Schedule 1, Part 2, omit entry for Sucralfate
15. Schedule 1, Part 2, omit entry for Tamoxifen
16. Schedule 1, Part 2, omit entry for Testosterone
17. Schedule 1, Part 2, omit entry for Verapamil
18. Schedule 3, details relevant to Responsible Person code DX

*omit from the column headed “Responsible Person”:* Ascensia Diabetes Care Australia Pty Ltd *substitute:* Ascensia Diabetes Care Australia Pty Limited

1. Schedule 3, details relevant to Responsible Person code EO

*omit from the column headed “Responsible Person”:* Ego Pharmaceuticals Proprietary Limited *substitute:* Ego Pharmaceuticals Pty Ltd

1. Schedule 3

*omit:*

|  |  |  |
| --- | --- | --- |
| ER | Eris Pharmaceuticals (Australia) Pty Ltd | 64 139 968 139 |

1. Schedule 3

*omit:*

|  |  |  |
| --- | --- | --- |
| XM | The Medicines Company (Australia) Pty Limited | 74 138 555 021 |

1. Schedule 3, after details relevant to Responsible Person code ZP

*insert:*

|  |  |  |
| --- | --- | --- |
| ZS | Strides Pharma Science Pty Ltd | 44 635 036 734 |

1. Schedule 4, Part 1, entry for Abatacept
   1. insert in numerical order after existing text:

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|  | C12378 | P12378 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |
|  | C12385 | P12385 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Initial treatment with an I.V. loading dose: Two completed authority prescriptions must be submitted with the initial application. One prescription must be for the I.V. loading dose for sufficient vials for one dose based on the patient's weight with no repeats. The second prescription must be written for the subcutaneous formulation, with a maximum quantity of 4 and up to 5 repeats. Initial treatment with no loading dose: One completed authority prescription must be submitted with the initial application. The prescription must be written with a maximum quantity of 4 and up to 5 repeats. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Abemaciclib
   1. substitute:

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| Abemaciclib | C12348 |  |  | Locally advanced or metastatic breast cancer Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have received treatment with this drug for this PBS indication prior to 1 November 2021; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND Patient must have been untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy at the time non-PBS supply was initiated; OR Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time of non-PBS supply was initiated; AND The treatment must be in combination with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant, where the patient had never been treated with endocrine therapy for advanced/metastatic disease at the time non-PBS supply was initiated; OR The treatment must be in combination with fulvestrant only, where at the time non-PBS supply was initiated, the patient had recurrent/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. Patient must not be premenopausal. | Compliance with Authority Required procedures |
|  | C12367 |  |  | Locally advanced or metastatic breast cancer Initial treatment Patient must be untreated with cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy; OR Patient must have developed an intolerance to another CDK4/6 inhibitor therapy (other than this drug) of a severity necessitating permanent treatment withdrawal; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND The condition must be inoperable; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND The treatment must be in combination, where the patient has never been treated with endocrine therapy for advanced/metastatic disease, with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant; OR The treatment must be in combination, where the patient has recurrence/progressive disease despite being treated with endocrine therapy for advanced/metastatic disease, with fulvestrant only; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. Patient must not be premenopausal. | Compliance with Authority Required procedures |
|  | C12380 |  |  | Locally advanced or metastatic breast cancer Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND The treatment must be in combination with one of: (i) anastrozole, (ii) letrozole, (iii) fulvestrant; AND The treatment must not be in combination with another cyclin-dependent kinase 4/6 (CDK4/6) inhibitor therapy. Patient must not be premenopausal. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Abiraterone
   1. substitute:

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| Abiraterone | C12352 |  |  | Castration resistant metastatic carcinoma of the prostate The treatment must be used in combination with a corticosteroid; AND The treatment must not be used in combination with chemotherapy; AND Patient must have a WHO performance status of 2 or less; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND Patient must not be undergoing treatment with this drug following treatment with any of: (i) darolutamide, (ii) enzalutamide; OR Patient must have developed an intolerance to enzalutamide of a severity necessitating permanent treatment withdrawal. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Acalabrutinib
   1. omit:

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|  | C10669 |  |  | Relapsed or refractory chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) Grandfather treatment (initial treatment in a patient commenced on non-PBS-subsidised treatment) Patient must have previously received non-PBS-subsidised treatment with this drug for relapsed or refractory CLL/SLL prior to 1 September 2020; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The condition must have relapsed or be refractory to at least one prior therapy prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have a WHO performance status of 1 or less prior to starting non-PBS treatment with this drug; AND Patient must have been considered unsuitable for treatment or retreatment with a purine analogue prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must be considered unsuitable for treatment or retreatment with a purine analogue; AND 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) prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR 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 prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition. A patient is considered unsuitable for treatment or retreatment with a purine analogue as demonstrated by at least one of the following being met prior to commencing non-PBS-subsidised treatment with this drug for this condition: 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; b) Age is 70 years or older; 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; d) History of purine analogue-associated autoimmune anaemia or autoimmune thrombocytopenia; e) Evidence of one or more 17p chromosomal deletions demonstrated by a Medical Benefits Schedule listed test. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Adalimumab
   1. insert in numerical order after existing text:

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|  | C12354 | P12354 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C12364 | P12364 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |
|  | C12366 | P12366 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |
|  | C12391 | P12391 |  | Severe active juvenile idiopathic arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, omit entry for Amino acid formula with fat, carbohydrate, vitamins, minerals and long chain polyunsaturated fatty acids without phenylalanine and supplemented with docosahexaenoic acid
2. Schedule 4, Part 1, entry for Baricitinib
   1. insert in numerical order after existing text:

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|  | C12354 | P12354 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C12366 | P12366 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Beclometasone with formoterol and glycopyrronium
   1. substitute:

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| Beclometasone with formoterol and glycopyrronium | C12349 |  |  | Chronic obstructive pulmonary disease (COPD) Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition. Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information. | Compliance with Authority Required procedures - Streamlined Authority Code 12349 |

1. Schedule 4, Part 1, entry for Bisacodyl

omit:

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|  |  | P6139 |  | Constipation Patient must be receiving palliative care. |  |

1. Schedule 4, Part 1, entry for Bortezomib

omit:

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|  | C7938 |  |  | Multiple myeloma Retreatment of Progressive disease - Initial PBS-subsidised treatment The treatment must be as monotherapy; OR The treatment must be in combination with a corticosteroid and/or cyclophosphamide; AND Patient must have progressive disease; AND Patient must have previously been treated with PBS-subsidised bortezomib; AND Patient must have experienced at least a partial response to the most recent course of PBS-subsidised bortezomib therapy; AND Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues; AND Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein). If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours. If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels. If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as: (a) at least a 50% reduction in bone marrow plasma cells; or (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L. Details of the basis of the current diagnosis of progressive disease and nomination of which disease activity parameters that will be used to assess response, and diagnostic reports demonstrating the patient has achieved at least a partial response to the most recent course of PBS-subsidised bortezomib, if not previously documented must be documented in the patient's medical records. Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (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) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters must be used to determine response, results for either (a) or (b) or (c) must be documented in the patient's medical records. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7938 |
|  | C7939 |  |  | Multiple myeloma Retreatment of Progressive disease - Continuing PBS-subsidised treatment The treatment must be as monotherapy; OR The treatment must be in combination with a corticosteroid and/or cyclophosphamide; AND Patient must have previously received 4 treatment cycles of bortezomib in the current treatment course; AND Patient must have demonstrated at the completion of cycle 4 at least a partial response to bortezomib; AND Patient must not have received 2 treatment cycles after first achieving a confirmed complete response; AND Patient must not have a gap of more than 6 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction. Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient's medical records. If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein). If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours. If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels. If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as: (a) at least a 50% reduction in bone marrow plasma cells; or (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L. Diagnostic reports must be no more than one month old at the time of prescribing. A response assessment prior to cycle 5 must be documented in the patient's medical records. Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart. | Compliance with Authority Required procedures - Streamlined Authority Code 7939 |
|  | C7940 |  |  | Symptomatic multiple myeloma Continuing PBS-subsidised treatment Patient must have received an initial authority prescription for bortezomib for newly diagnosed symptomatic multiple myeloma and be ineligible for high dose chemotherapy; AND Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND Patient must not have achieved a best confirmed response to bortezomib at the time of prescribing; 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 5 cycles of treatment with bortezomib under this restriction. Continuing PBS-subsidised supply requires that the gap between the initial PBS-subsidised treatment with this drug for this condition and this continuing treatment is no more than 6 months. | Compliance with Authority Required procedures - Streamlined Authority Code 7940 |
|  | C7941 |  |  | Symptomatic multiple myeloma Continuing PBS-subsidised treatment Patient must have previously received PBS-subsidised treatment with this drug for newly diagnosed symptomatic multiple myeloma; AND Patient must have severe acute renal failure; AND Patient must have demonstrated at least a partial response at the completion of cycle 4; 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 5 cycles of treatment with bortezomib under this restriction. A copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology authority and diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient's medical records. If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein). If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours. If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels. If serum M protein and urine Bence-Jones protein and serum FLC are not being used to monitor disease activity, partial response compared with baseline is defined as: (a) at least a 50% reduction in bone marrow plasma cells; or (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L. Continuing PBS-subsidised supply requires that the gap between the initial PBS-subsidised treatment with this drug for this condition and this continuing treatment is no more than 6 months. | Compliance with Authority Required procedures - Streamlined Authority Code 7941 |
|  | C7960 |  |  | Multiple myeloma Retreatment of Progressive disease - Continuing PBS-subsidised treatment The treatment must be as monotherapy; OR The treatment must be in combination with a corticosteroid and/or cyclophosphamide; AND Patient must have previously received 8 treatment cycles of bortezomib in the current treatment course; AND Patient must have demonstrated at the completion of cycle 8 at least a partial response to bortezomib; AND Patient must not have received 2 treatment cycles after first achieving a confirmed complete response; AND Patient must not have a gap of more than 10 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition following completion of 8 treatment cycles; AND Patient must not receive more than 3 cycles of bortezomib under this restriction. Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient's medical records. If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein). If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours. If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels. If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as: (a) at least a 50% reduction in bone marrow plasma cells; or (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L. Diagnostic reports must be no more than one month old at the time of prescribing. A response assessment prior to cycle 9 must be documented in the patient's medical records. Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart. | Compliance with Authority Required procedures - Streamlined Authority Code 7960 |
|  | C7961 |  |  | Multiple myeloma Treatment of Progressive disease - Initial PBS-subsidised treatment The condition must be confirmed by a histological diagnosis; AND The treatment must be as monotherapy; OR The treatment must be in combination with a corticosteroid and/or cyclophosphamide; AND Patient must have progressive disease after at least one prior therapy; AND Patient must have undergone or be ineligible for a primary stem cell transplant; AND Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues; AND Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response must be documented in the patient's medical records. Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (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) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters must be used to determine response, results for either (a) or (b) or (c) should be provided 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) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 7961 |
|  | C7962 |  |  | Multiple myeloma Treatment of Progressive disease - Continuing PBS-subsidised treatment The treatment must be as monotherapy; OR The treatment must be in combination with a corticosteroid and/or cyclophosphamide; AND Patient must have previously received 8 treatment cycles of bortezomib for progressive disease; AND Patient must have demonstrated at the completion of cycle 8 at least a partial response to bortezomib; AND Patient must not have received 2 treatment cycles after first achieving a confirmed complete response; AND Patient must not have a gap of more than 10 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition following completion of 8 treatment cycles; AND Patient must not receive more than 3 cycles of bortezomib under this restriction. Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient's medical records. If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein). If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours. If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels. If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as: (a) at least a 50% reduction in bone marrow plasma cells; or (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L. Diagnostic reports must be no more than one month old at the time of prescribing. A response assessment prior to cycle 9 must be documented in the patient's medical records. Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart. | Compliance with Authority Required procedures - Streamlined Authority Code 7962 |
|  | C7974 |  |  | Multiple myeloma Treatment of Progressive disease - Continuing PBS-subsidised treatment The treatment must be as monotherapy; OR The treatment must be in combination with a corticosteroid and/or cyclophosphamide; AND Patient must have previously received 4 treatment cycles of bortezomib for progressive disease; AND Patient must have demonstrated at the completion of cycle 4 at least a partial response to bortezomib; AND Patient must not have received 2 treatment cycles after first achieving a confirmed complete response; AND Patient must not have a gap of more than 6 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition; AND Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction. Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient's medical records. If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein). If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours. If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels. If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as: (a) at least a 50% reduction in bone marrow plasma cells; or (b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or (c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or (d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L. Diagnostic reports must be no more than one month old at the time of prescribing. A response assessment prior to cycle 5 must be documented in the patient's medical records. Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart. | Compliance with Authority Required procedures - Streamlined Authority Code 7974 |
|  | C10338 |  |  | Symptomatic multiple myeloma Patient must be newly diagnosed; AND Patient must be eligible for high dose chemotherapy and autologous stem cell transplantation; AND Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues; AND The treatment must be in combination with chemotherapy. Details of the histological diagnosis of multiple myeloma must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 10338 |
|  | C10426 |  |  | Symptomatic multiple myeloma Initial PBS-subsidised treatment The condition must be newly diagnosed; AND Patient must have severe acute renal failure; AND Patient must require dialysis; OR Patient must be at high risk of requiring dialysis in the opinion of a nephrologist; AND The treatment must be in combination with a corticosteroid and/or cyclophosphamide; AND Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues; AND Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction. Details of the histological diagnosis of multiple myeloma, the name of the nephrologist who has reviewed the patient and the date of review, a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology Authority, and nomination of the disease activity parameter(s) that will be used to assess response must be documented in the patient's medical records. Disease activity parameters include current diagnostic reports of at least one of the following: (a) the level of serum monoclonal protein; or (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or (c) in oligo-secretory and non-secretory myeloma patients only, the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. Magnetic Resonance Imaging (MRI) or computed tomography (CT) scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters will be used to determine response, results for either (a) or (b) or (c) should be documented in the patient's medical records for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 10426 |
|  | C10454 |  |  | Multiple myeloma Triple combination therapy (bortezomib, lenalidomide and dexamethasone) The condition must be newly diagnosed; AND The treatment must be in combination with lenalidomide and dexamethasone; AND The treatment must not be in combination with PBS-subsidised thalidomide, pomalidomide or carfilzomib; AND The treatment must not be changing from dual combination therapy with lenalidomide and dexamethasone for symptomatic multiple myeloma to triple therapy with lenalidomide, bortezomib and dexamethasone; AND Patient must not receive more than 8 cycles of treatment with bortezomib under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 10454 |
|  | C10455 |  |  | Symptomatic multiple myeloma Initial PBS-subsidised treatment The condition must be newly diagnosed; AND Patient must be ineligible for high dose chemotherapy; AND Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues; AND The treatment must be in combination with a corticosteroid and melphalan or cyclophosphamide; AND Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 10455 |

1. Schedule 4, Part 1, entry for Botulinum toxin type A purified neurotoxin complex
   1. omit:

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|  | C10298 |  |  | Moderate to severe spasticity of the upper limb following an acute event Grandfather treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2020; AND The condition must have been moderate to severe spasticity of the upper limb/s following an acute event, defined as a Modified Ashworth Scale rating of 3 or more prior to commencing non-PBS subsidised treatment; AND The treatment must only be used as second line therapy when standard management has failed; OR The treatment must only be used as an adjunct to physical therapy; AND The treatment must not continue if the patient did not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A); AND The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per upper limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per upper limb each year thereafter; AND Patient must not have established severe contracture in the limb to be treated. Patient must be aged 18 years or older. Must be treated by a neurologist; OR Must be treated by an orthopaedic surgeon; OR Must be treated by a rehabilitation specialist; OR Must be treated by a plastic surgeon; OR Must be treated by a geriatrician. Standard management includes physiotherapy and/or oral spasticity agents. | Compliance with Authority Required procedures - Streamlined Authority Code 10298 |

1. Schedule 4, Part 1, after entry for Budesonide with formoterol
   1. insert:

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| Budesonide with glycopyrronium and formoterol | C12349 |  |  | Chronic obstructive pulmonary disease (COPD) Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition. Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information. | Compliance with Authority Required procedures - Streamlined Authority Code 12349 |

1. Schedule 4, Part 1, entry for Certolizumab pegol
   * 1. omit:

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|  | C10458 | P10458 |  | Non-radiographic axial spondyloarthritis Grandfather treatment Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 June 2020; AND Patient must have had chronic lower back pain and stiffness for 3 or more months that was relieved by exercise but not rest, prior to initiating non-PBS subsidised treatment with this drug for this condition; AND Patient must have had failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had one or more of the following: (a) enthesitis (heel); (b) uveitis; (c) dactylitis; (d) psoriasis; (e) inflammatory bowel disease; or (f) positive for Human Leukocyte Antigen B27 (HLA-B27); prior to initiating non-PBS subsidised treatment with this drug for this condition; AND The condition must not be radiographically evidenced on plain x-ray of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis prior to commencing non-PBS subsidised treatment with this biological medicine; AND The condition must have been diagnosed as non-radiographic axial spondyloarthritis, as defined by Assessment of Spondyloarthritis International Society (ASAS) criteria, prior to having commenced non-PBS subsidised treatment with this biological medicine; AND The condition must have been sacroiliitis with active inflammation and/or oedema on non-contrast Magnetic Resonance Imaging (MRI) prior to commencing non-PBS subsidised treatment with this biological medicine; AND The condition must have had presence of Bone Marrow Oedema (BMO) depicted as a hyperintense signal on a Short Tau Inversion Recovery (STIR) image (or equivalent) prior to commencing non-PBS subsidised treatment with this biological medicine; AND The condition must have had BMO depicted as a hypointense signal on a T1 weighted image (without gadolinium) prior to commencing non-PBS subsidised treatment with this biological medicine; AND The treatment must not exceed a maximum of 24 weeks with this drug under this restriction. Patient must be aged 18 years or older. Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of non-radiographic axial spondyloarthritis. The application must include details of the NSAIDs trialled, their doses and duration of treatment. If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used. If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication. If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance. The following criteria indicate failure to achieve an adequate response to NSAIDs and must have been demonstrated prior to initiation of non-PBS subsidised treatment with this biological medicine for this condition: (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of at least 4 on a 0-10 scale; and (b) C-reactive protein (CRP) level greater than 10 mg per L. The BASDAI score and CRP level must have been determined at the completion of the 3-month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measures must have been no more than 1 month old at the time of initiating non-PBS subsidised treatment with this biological medicine for this condition. If the requirement to demonstrate an elevated CRP level could not be met, the reason must be stated in the application. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason. The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria. The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Non-radiographic axial spondyloarthritis Grandfathered PBS Authority Application - Supporting Information Form which seeks details of: (i) a copy of the radiological report confirming the absence of Grade II bilateral sacroiliitis or Grade III or IV unilateral sacroiliitis; and (ii) a BASDAI score and CRP level that substantiates failure to achieve an adequate response to NSAIDs prior to initiating non-PBS subsidised treatment with this biological medicine for this condition; and (iii) the MRI report; and (iv) the NSAIDs trialled, their doses and duration of treatment. If applicable, the reason a higher dose cannot be used where the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information or details of the contraindication or intolerance according to the relevant TGA-approved Product Information must be included. The baseline BASDAI score and CRP level must also be documented in the patient's medical records. | Compliance with Written Authority Required procedures |

* + 1. omit:

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|  | 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 Authority Required procedures |

* + 1. insert in numerical order after existing text:

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|  | C12354 | P12354 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C12366 | P12366 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |
|  | C12392 | P12392 |  | Non-radiographic axial spondyloarthritis Continuing treatment - 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; AND The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing 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 |
|  | C12393 | P12393 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - Balance of Supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) restriction to complete 24 weeks treatment, depending on the dosage regimen; AND The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Daratumumab
   * 1. omit:

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|  | C11142 |  |  | Relapsed and/or refractory multiple myeloma Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly) The condition must be confirmed by a histological diagnosis; AND The treatment must be in combination with bortezomib and dexamethasone; AND Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised); AND Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues; AND Patient must not have previously received this drug for this condition. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records. Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (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) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented 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) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records. A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner. A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease. | Compliance with Authority Required procedures |

* + 1. insert in numerical order after existing text:

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|  | C12350 | P12350 |  | Relapsed and/or refractory multiple myeloma Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly) The condition must be confirmed by a histological diagnosis; AND The treatment must be in combination with bortezomib and dexamethasone; AND Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised); AND Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues. Patient must be undergoing treatment with this drug in one of the following situations: (i) for the first time, (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records. Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (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) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented 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) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records. A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner. A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease. | Compliance with Authority Required procedures |
|  | C12369 | P12369 |  | Relapsed and/or refractory multiple myeloma Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements Patient must have been on treatment with this drug in the subcutaneous form for this condition prior to 1 November 2021; AND Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (i) the condition was confirmed by histological diagnosis, (ii) the treatment is/was being used as part of triple combination therapy with bortezomib and dexamethasone, (iii) the condition progressed (see definition of progressive disease below) after one prior therapy, but not after more than two prior lines of therapies (i.e. this drug was commenced as second-line treatment), (iv) the treatment was/is not to be used in combination with PBS-subsidised carfilzomib, thalidomide or its analogues, and (v) the patient had never been treated with this drug; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues. Progressive disease is defined as at least 1 of the following: (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause). Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records. Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records: (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) the serum level of free kappa and lambda light chains; or (d) bone marrow aspirate or trephine; or (e) if present, the size and location of lytic bone lesions (not including compression fractures); or (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or (g) if present, the level of hypercalcaemia, corrected for albumin concentration. As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented 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) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records. A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner. A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, after entry for Darbepoetin alfa
   1. insert:

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| Darolutamide | C12398 |  |  | Castration resistant non-metastatic carcinoma of the prostate The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition; AND The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug. Patient must be undergoing concurrent treatment with androgen deprivation therapy. Prescribing instructions: Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application. The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months anytime prior to first commencing treatment with this drug. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, omit entry for Diclofenac
2. Schedule 4, Part 1, entry for Electrolyte replacement, oral
   * 1. omit from the column headed “Purposes Code” for circumstances code “C5889”: P5889
     2. omit from the column headed “Purposes Code” for circumstances code “C6786”: P6786
3. Schedule 4, Part 1, entry for Entrectinib
   1. omit:

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|  | C10672 |  |  | Stage IIIB (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Grandfather treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2020; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND The treatment must be as monotherapy; AND Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition; AND Patient must not have received prior treatment with a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor for this condition prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed intolerance to a c-ROS proto-oncogene 1 (ROS1) receptor tyrosine kinase inhibitor necessitating permanent treatment withdrawal prior to initiating non-PBS-subsidised treatment with this drug for this condition; AND Patient must have evidence of c-ROS proto-oncogene 1 (ROS1) gene rearrangement in tumour material, defined as 15% (or greater) positive cells by fluorescence in situ hybridisation (FISH) testing prior to initiating non-PBS subsidised treatment with this drug for this condition. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Non-Small-Cell Lung Cancer Authority Application - Supporting Information Form. 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. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Enzalutamide
   1. substitute:

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| Enzalutamide | C12371 |  |  | Castration resistant metastatic carcinoma of the prostate The treatment must not be used in combination with chemotherapy; AND Patient must have a WHO performance status of 2 or less; AND Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; AND Patient must not be undergoing treatment with this drug following treatment with any of: (i) darolutamide, (ii) abiraterone; OR Patient must have developed an intolerance to abiraterone of a severity necessitating permanent treatment withdrawal. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Etanercept
   1. insert in numerical order after existing text:

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|  | C12354 | P12354 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C12359 | P12359 |  | Severe active juvenile idiopathic arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) completed authority prescription form(s); and (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |
|  | C12366 | P12366 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |
|  | C12389 | P12389 |  | Severe active juvenile idiopathic arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) an active joint count of fewer than 10 active (swollen and tender) joints; or (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or (c) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction. If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Evolocumab
   * 1. omit:

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|  | C10358 | P10358 |  | Non-familial hypercholesterolaemia Grandfather treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2020; AND The treatment must be in conjunction with dietary therapy and exercise; AND Patient must have had symptomatic atherosclerotic cardiovascular disease prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had an LDL cholesterol level in excess of 2.6 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories) prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had diabetes mellitus with microalbuminuria prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had diabetes mellitus and be aged 60 years of more prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must be an Aboriginal or Torres Strait Islander with diabetes mellitus that was present prior to starting non-PBS-subsidised treatment with this drug for this condition; OR Patient must have had a Thrombolysis in Myocardial Infarction (TIMI) Risk Score for Secondary Prevention of 4 or higher prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition. Must be treated by a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal. In the event of a trial of the alternative statin, the dose of the alternative statin should have been increased not more often than every 4 weeks until the maximum tolerated dose was reached or target LDL-c had been achieved. One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. One or more of the following must be stated at the time of application and documented in the patient's medical records regarding the presence of cardiovascular disease or high risk of experiencing a cardiovascular event: (i) atherosclerotic disease in two or more vascular territories (coronary, cerebrovascular or peripheral vascular territories); or (ii) severe multi-vessel coronary heart disease defined as at least 50% stenosis in at least two large vessels; or (iii) history of at least two major cardiovascular events (i.e. myocardial infarction, unstable angina, stroke or unplanned revascularisation) in the previous 5 years; or (iv) diabetes mellitus with microalbuminuria; or (v) diabetes mellitus and age 60 years of more; or (vi) Aboriginal or Torres Strait Islander with diabetes mellitus; or (vii) a Thrombolysis in Myocardial Infarction (TIMI) risk score for secondary prevention of 4 or higher 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. | Compliance with Authority Required procedures |
|  | C10370 | P10370 |  | Familial homozygous hypercholesterolaemia Grandfather treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2020; AND The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 7 prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had an LDL cholesterol level in excess of 2.6 millimoles per litre prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information. Must be treated by a specialist physician. The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of treatment with a statin (unless treatment with a statin is contraindicated or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. The following must be stated at the time of application and documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial homozygous hypercholesterolaemia One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the dose, duration of treatment and details of adverse events experienced with the trial of atorvastatin or rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information 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. | Compliance with Authority Required procedures |

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|  | C10389 | P10389 |  | Familial heterozygous hypercholesterolaemia Grandfather treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2020; AND The treatment must be in conjunction with dietary therapy and exercise; AND The condition must have been confirmed by genetic testing prior to starting non-PBS-subsidised treatment with this drug for this condition; OR The condition must have been confirmed by a Dutch Lipid Clinic Network Score of at least 6 prior to starting non-PBS-subsidised treatment with this drug for this condition; AND Patient must have had an LDL cholesterol level in excess of 2.6 millimoles per litre in the presence of symptomatic atherosclerotic cardiovascular disease at the time non-PBS-subsidised treatment with this drug for this condition was initiated; OR Patient must have had an LDL cholesterol level in excess of 5 millimoles per litre at the time non-PBS-subsidised treatment with this drug for this condition was initiated; AND Patient must have been treated with the maximum recommended dose of atorvastatin (80 mg daily) or rosuvastatin (40 mg daily) according to the TGA-approved Product Information or the maximum tolerated dose of atorvastatin or rosuvastatin for at least 12 consecutive weeks in conjunction with dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must have developed a clinically important product-related adverse event necessitating withdrawal of statin treatment to trials of each of atorvastatin and rosuvastatin prior to initiating non-PBS-subsidised treatment with this drug for this condition; OR Patient must be contraindicated to treatment with a HMG CoA reductase inhibitor (statin) as defined in the TGA-approved Product Information; AND Patient must have been treated with ezetimibe for at least 12 consecutive weeks in conjunction with a statin (if tolerated), dietary therapy and exercise prior to initiating non-PBS-subsidised treatment with this drug for this condition. Must be treated by a specialist physician. Symptomatic atherosclerotic cardiovascular disease is defined as: (i) the presence of symptomatic coronary artery disease (prior myocardial infarction, prior revascularisation procedure, angina associated with demonstrated significant coronary artery disease (50% or greater stenosis in 1 or more coronary arteries on imaging), or positive functional testing (e.g. myocardial perfusion scanning or stress echocardiography); or (ii) the presence of symptomatic cerebrovascular disease (prior ischaemic stroke, prior revascularisation procedure, or transient ischaemic attack associated with 50% or greater stenosis in 1 or more cerebral arteries on imaging); or (iii) the presence of symptomatic peripheral arterial disease (prior acute ischaemic event due to atherosclerosis, prior revascularisation procedure, or symptoms of ischaemia with evidence of significant peripheral artery disease (50% or greater stenosis in 1 or more peripheral arteries on imaging)). The qualifying LDL cholesterol level must have been measured following at least 12 consecutive weeks of combined treatment with a statin, ezetimibe, dietary therapy and exercise (unless treatment with a statin is contraindicated, or following completion of statin trials as described in these prescriber instructions in the event of clinically important adverse events), must be stated at the time of application, documented in the patient's medical records and must have been no more than 8 weeks old at the time non-PBS-subsidised treatment with this drug for this condition was initiated. A clinically important product-related adverse event is defined as follows: (i) Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or (ii) Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or (iii) Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin. If treatment with atorvastatin or rosuvastatin resulted in development of a clinically important product-related adverse event resulting in treatment withdrawal, the patient must have been treated with the alternative statin (atorvastatin or rosuvastatin) unless there was a contraindication (e.g. prior rhabdomyolysis) to the alternative statin. This retrial should have occurred after a washout period of at least 4 weeks, or if the creatine kinase (CK) level was elevated, the retrial should not have occurred until CK had returned to normal. In the event of a trial of the alternative statin, the dose of the alternative statin should have been increased not more often than every 4 weeks until the maximum tolerated dose was reached or target LDL-c had been achieved. The following must be stated at the time of application and documented in the patient's medical records: (i) the qualifying Dutch Lipid Clinic Network Score; or (ii) the result of genetic testing confirming a diagnosis of familial heterozygous hypercholesterolaemia One of the following must be stated at the time of application and documented in the patient's medical records regarding prior statin treatment: (i) the patient was treated with atorvastatin 80 mg or rosuvastatin 40 mg or the maximum tolerated dose of either for 12 consecutive weeks; or (ii) the doses, duration of treatment and details of adverse events experienced with trials with each of atorvastatin and rosuvastatin; or (iii) the patient is contraindicated to treatment with a statin as defined in the TGA-approved Product Information. 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. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Fluticasone furoate with umeclidinium and vilanterol
   1. substitute:

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| Fluticasone furoate with umeclidinium and vilanterol | C12349 |  |  | Chronic obstructive pulmonary disease (COPD) Patient must have experienced at least one severe COPD exacerbation, which required hospitalisation, or two or more moderate exacerbations in the previous 12 months, with significant symptoms despite regular bronchodilator therapy with a long acting muscarinic antagonist (LAMA) and a long acting beta-2 agonist (LABA) or an inhaled corticosteroid (ICS) and a LABA; OR Patient must have been stabilised on a combination of a LAMA, LABA and an ICS for this condition. Patient must not be undergoing treatment with this product in each of the following circumstances: (i) treatment of asthma in the absence of a COPD diagnosis, (ii) initiation of bronchodilator therapy in COPD, (iii) use as reliever therapy for asthma, (iv) dosed at an interval/frequency that differs to that recommended in the approved Product Information. | Compliance with Authority Required procedures - Streamlined Authority Code 12349 |

1. Schedule 4, Part 1, entry for Golimumab
   1. insert in numerical order after existing text:

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|  | C12354 | P12354 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C12366 | P12366 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, omit entry for Grazoprevir with elbasvir
2. Schedule 4, Part 1, entry for High fat formula with vitamins, minerals and trace elements and low in protein and carbohydrate

omit:

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| --- | --- | --- | --- | --- | --- |
|  | C6858 |  |  | Ketogenic diet Patient must have intractable seizures requiring treatment with a ketogenic diet; OR Patient must have a glucose transport protein defect; OR Patient must have pyruvate dehydrogenase deficiency. Keyo should only be used under strict supervision of a dietitian, together with a metabolic physician and/or neurologist. |  |

1. Schedule 4, Part 1, entry for IncobotulinumtoxinA
   1. omit:

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| --- | --- | --- | --- | --- | --- |
|  | C10594 |  |  | Moderate to severe spasticity of the upper limb following an acute event Grandfather treatment Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2020; AND The condition must have been moderate to severe spasticity of the upper limb/s following an acute event, defined as a Modified Ashworth Scale rating of 3 or more prior to commencing non-PBS subsidised treatment; AND The treatment must only be used as second line therapy when standard management has failed; OR The treatment must only be used as an adjunct to physical therapy; AND The treatment must not continue if the patient did not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A); AND The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per upper limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per upper limb each year thereafter; AND Patient must not have established severe contracture in the limb to be treated. Patient must be aged 18 years or older. Must be treated by a neurologist; OR Must be treated by an orthopaedic surgeon; OR Must be treated by a rehabilitation specialist; OR Must be treated by a plastic surgeon; OR Must be treated by a geriatrician. Standard management includes physiotherapy and/or oral spasticity agents. | Compliance with Authority Required procedures - Streamlined Authority Code 10594 |

1. Schedule 4, Part 1, entry for Infliximab
   1. insert in numerical order after existing text:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C12363 | P12363 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - Balance of Supply Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received insufficient therapy with this drug for this condition under the Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) restriction, with subcutaneous form restriction to complete 22 weeks initial treatment (intravenous and subcutaneous inclusive); AND The treatment must provide no more than the balance of up to 22 weeks treatment available under the - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) - subcutaneous form. Patient must be aged 18 years or older. | Compliance with Authority Required procedures |
|  | C12378 | P12378 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly; AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |
|  | C12390 | P12390 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - Change of treatment due to critical shortage of tocilizumab) - subcutaneous form at weeks 6, 8, 10, 12, 14 and 16 Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must have received 2 intravenous infusions with this drug for this condition at weeks 0 and 2 under Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times; AND The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly. Patient must be aged 18 years or older. If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Leuprorelin
   * 1. omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C6422 |  |  | Central precocious puberty Continuing treatment Must be treated by a medical practitioner in consultation with a paediatric endocrinologist; OR Must be treated by a medical practitioner in consultation with an endocrinologist specialising in paediatrics. Patient must have previously been issued with an authority prescription for this drug for this condition. |  |

* + 1. omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C6426 |  |  | Central precocious puberty Initial - grandfather Patient must have received treatment with a gonadotropin releasing hormone analogue (GnRHa) for this condition prior to 1 May 2015. Must be treated by a paediatric endocrinologist; OR Must be treated by an endocrinologist specialising in paediatrics. |  |

* + 1. insert in numerical order after existing text:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C12351 |  |  | Central precocious puberty Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication. |  |

1. Schedule 4, Part 1, entry for Lorlatinib
   1. omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C10563 |  |  | Stage IV (metastatic) non-small cell lung cancer (NSCLC) Grandfather treatment Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 August 2020; AND The treatment must be as monotherapy; AND The condition must be non-squamous type non-small cell lung cancer (NSCLC) or not otherwise specified type NSCLC; AND Patient must have had a WHO performance status of 2 or less prior to initiating non-PBS-subsidised treatment; AND The condition must have progressed following treatment with an ALK inhibitor other than crizotinib prior to commencement of non-PBS-subsidised treatment with this drug for this PBS indication; AND Patient must not have progressive disease while receiving treatment with this drug for this condition. Patient must have evidence of an anaplastic lymphoma kinase (ALK) gene rearrangement. 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. | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Tamoxifen

omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C6470 |  |  | Breast cancer The condition must be hormone receptor positive. | C6470 |

1. Schedule 4, Part 1, entry for Tofacitinib
   1. insert in numerical order after existing text:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C12354 | P12354 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C12366 | P12366 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |

1. Schedule 4, Part 1, entry for Triptorelin
   1. insert in numerical order after existing text:

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| --- | --- | --- | --- | --- | --- |
|  | C12351 |  |  | Central precocious puberty Continuing treatment with this drug, or, switching gonadotropin releasing hormone analogue therapy Must be treated by a medical practitioner identifying as one of: (i) a paediatric endocrinologist, (ii) an endocrinologist specialising in paediatrics; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion; AND Patient must be undergoing continuing treatment with a gonadotropin releasing hormone analogue initiated through the PBS for this PBS indication. |  |
|  | C12387 |  |  | Central precocious puberty Initial treatment Must be treated by a paediatric endocrinologist; OR Must be treated by an endocrinologist specialising in paediatrics. Patient must be of an age that is prior to their 12thbirthday if female; OR Patient must be of an age that is prior to their 13thbirthday if male; AND Patient must have had onset of signs/symptoms of central precocious puberty prior to their 9thbirthday if female; OR Patient must have had onset of signs/symptoms of central precocious puberty prior to their 10thbirthday if male. |  |
|  | C12397 |  |  | Central precocious puberty Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements Must be treated by a paediatric endocrinologist; OR Must be treated by an endocrinologist specialising in paediatrics; OR Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion. Patient must be each of: (i) currently receiving this drug for the PBS-indication, (ii) commenced on non-PBS-subsidised supply prior to 1 November 2021. Patient must have met each of: (i) experienced signs/symptoms of central precocious puberty prior to their 9thbirthday, (ii) initiated treatment with this drug prior to their 12thbirthday, if female; OR Patient must have met each of: (i) experienced signs/symptoms of central precocious puberty prior to their 10thbirthday, (ii) initiated treatment with this drug prior to their 13thbirthday, if male. |  |

1. Schedule 4, Part 1, entry for Upadacitinib
   1. insert in numerical order after existing text:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C12354 | P12354 |  | Severe active rheumatoid arthritis Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab) Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021; AND The treatment must be in place of tocilizumab due to the critical supply shortage of tocilizumab; AND Patient must not receive more than 24 weeks of treatment under this restriction; AND Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition; AND Patient must not have already failed , or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 5 times. Patient must be aged 18 years or older. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). If a patient has received 12 weeks or more of therapy with tocilizumab as their most recent treatment, evidence of a response must be provided. If a patient has not received a minimum of 12 weeks therapy with tocilizumab, evidence of a response is not required to be provided under this restriction. This switch in therapy from tocilizumab will not be counted as treatment failure to tocilizumab. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. | Compliance with Written Authority Required procedures |
|  | C12366 | P12366 |  | Severe active rheumatoid arthritis First continuing treatment - Critical shortage of tocilizumab - Temporary listing Must be treated by a rheumatologist; OR Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis. Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under Initial treatment - Initial 4 (Temporary listing - change of treatment due to critical shortage of tocilizumab); AND Patient must have demonstrated an adequate response to treatment with this drug; AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction. Patient must be aged 18 years or older. An adequate response to treatment is defined as: an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; AND either of the following: (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or (b) a reduction in the number of the following active joints, from at least 4, by at least 50%: (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth). Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition. If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence of a response to this drug is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved. | Compliance with Written Authority Required procedures |

1. Schedule 5, entry for Imatinib in the form Tablet 100 mg (as mesilate) *[GRP-21076]*
   1. insert in alphabetical order in the column headed “Brand” Imatinib-Teva
2. Schedule 5, after entry for Imatinib in the form Tablet 100 mg (as mesilate) *[GRP-21076]*
   1. insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | GRP-25645 | Capsule 100 mg (as mesilate) | Oral | IMATINIB-DRLA Imatinib-APOTEX |
|  |  | Tablet 100 mg (as mesilate) | Oral | Gilmat Glivec Imatinib-Teva |
|  | GRP-25646 | Capsule 100 mg (as mesilate) | Oral | IMATINIB-DRLA |
|  |  | Tablet 100 mg (as mesilate) | Oral | Gilmat Glivec Imatinib-Teva |

1. Schedule 5, entry for Imatinib in the form Tablet 400 mg (as mesilate) *[GRP-21080]*
   1. insert in alphabetical order in the column headed “Brand”: Imatinib-Teva
2. Schedule 5, after entry for Imatinib in the form Tablet 400 mg (as mesilate) *[GRP-21080]*
   1. insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | GRP-25647 | Capsule 400 mg (as mesilate) | Oral | IMATINIB-DRLA |
|  |  | Tablet 400 mg (as mesilate) | Oral | Gilmat Glivec Imatinib-Teva |
|  | GRP-25684 | Capsule 400 mg (as mesilate) | Oral | IMATINIB-DRLA Imatinib-APOTEX |
|  |  | Tablet 400 mg (as mesilate) | Oral | Gilmat Glivec Imatinib-Teva |

1. Schedule 5, entry for Perindopril with indapamide in the form Tablet containing perindopril erbumine 4 mg with indapamide hemihydrate 1.25 mg
   1. insert in alphabetical order in the column headed “Brand”: APO-Perindopril/Indapamide
2. Schedule 5, omit entry for Pindolol
3. Schedule 5, after entry for Tiotropium in the form Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in HandiHaler) *[GRP-23704]*
   1. insert:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Tocilizumab | GRP-25653 | Concentrate for injection 400 mg in 20 mL | Injection | Actemra |
|  |  | Concentrate for injection 400 mg in 20 mL s19A | Injection | RoActemra |
|  | GRP-25663 | Concentrate for injection 80 mg in 4 mL | Injection | Actemra |
|  |  | Concentrate for injection 80 mg in 4 mL s19A | Injection | RoActemra |
|  | GRP-25697 | Concentrate for injection 200 mg in 10 mL | Injection | Actemra |
|  |  | Concentrate for injection 200 mg in 10 mL s19A | Injection | RoActemra |