**PB 27 of 2022**

# National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (April Update) Instrument 2022

*National Health Act 1953*

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I, DAVID LAFFAN, Assistant Secretary, Pharmacy Branch, Technology Assessment and Access Division, Department of Health, delegate of the Minister for Health and Aged Care, make this Instrument under subsection 100(2) of the *National Health Act 1953*.

Date 29 March 2022

**DAVID LAFFAN**
Assistant Secretary
Pharmacy Branch
Technology Assessment and Access Division

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# Contents

## 1 Name

(1) This instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (April Update) Instrument 2022*.

(2) This instrument may also be cited as PB 27 of 2022.

## 2 Commencement

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

| **Commencement information** | | |
|---|---|---|
| **Column 1** | **Column 2** | **Column 3** |
| **Provisions** | **Commencement** | **Date/Details** |
| 1. *The whole of this instrument* | *1 April 2022* | *1 April 2022* |

Note: This table relates only to the provisions of this instrument as originally made.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

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

## 3 Authority

This instrument is made under subsection 100(2) of the *National Health Act 1953*.

## 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

# Schedule 1—Amendments

## *National Health (Highly Specialised Drugs Program) Special Arrangement 2021 (PB 27 of 2021)*

**[1] Section 6, definition for "CAR drug"**

*substitute:*

***CAR drug*** (short for Complex Authority Required drug) means any of the following highly specialised drugs:

(a) abatacept;
(b) adalimumab;
(c) ambrisentan;
(d) azacitidine;
(e) benralizumab;
(f) bosentan;
(g) dupilumab;
(h) eculizumab;
(i) elexacaftor with tezacaftor and with ivacaftor, and ivacaftor;
(j) eltrombopag;
(k) epoprostenol;
(l) etanercept;
(m) iloprost;
(n) infliximab;
(o) ivacaftor;
(p) lenalidomide;
(q) lumacaftor with ivacaftor;
(r) macitentan;
(s) mepolizumab;
(t) midostaurin;
(u) nusinersen;

(v) omalizumab;
(w) pasireotide;
(x) pegvisomant;
(y) pomalidomide;
(z) ravulizumab
(aa) riociguat;
(bb) risdiplam
(cc) rituximab;
(dd) romiplostim;
(ee) sildenafil;
(ff) tadalafil;
(gg) teduglutide;
(hh) tezacaftor with ivacaftor and ivacaftor;
(ii) tocilizumab;
(jj) ustekinumab;
(kk) vedolizumab.

**[2] Section 6, definition for "medication for the treatment of HIV or AIDS"**

*substitute:*

***medication for the treatment of HIV or AIDS*** means any of the following:

(a) abacavir;
(b) abacavir with lamivudine;
(c) abacavir with lamivudine and zidovudine;
(d) atazanavir;
(e) atazanavir with cobicistat;
(f) azithromycin;
(g) bictegravir with emtricitabine with tenofovir alafenamide;
(h) cabotegravir;

(i) cabotegravir and rilpivirine;
(j) darunavir;
(k) darunavir with cobicistat;
(l) darunavir with cobicistat, emtricitabine and tenofovir alafenamide;
(m) dolutegravir;
(n) dolutegravir with abacavir and lamivudine;
(o) dolutegravir with lamivudine;
(p) dolutegravir with rilpivirine;
(q) doxorubicin - pegylated liposomal;
(r) efavirenz;
(s) emtricitabine with rilpivirine with tenofovir alafenamide;
(t) emtricitabine with tenofovir alafenamide;
(u) enfuvirtide;
(v) etravirine;
(w) fosamprenavir;
(x) ganciclovir;
(y) lamivudine;
(z) lamivudine with zidovudine;
(aa) lopinavir with ritonavir;
(bb) maraviroc;
(cc) nevirapine;
(dd) raltegravir;
(ee) rifabutin;
(ff) rilpivirine;
(gg) ritonavir;
(hh) saquinavir;
(ii) tenofovir;
(jj) tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat;

(kk) tenofovir with emtricitabine;

(ll) tenofovir with emtricitabine and efavirenz;

(mm) tipranavir;

(nn) valganciclovir;

(oo) zidovudine.

**[3] Schedule 1, entry for Azacitidine**

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

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | Azacitidine MSN | C6132 C6143 C6144 C6177 C6186 C6199 C12439 | See Schedule 2 | See Schedule 2 |

**[4] Schedule 1, after entry for Bosentan in the form Tablet 125 mg (as monohydrate)**

*insert:*

| | | | | | | |
|---|---|---|---|---|---|---|
| Cabotegravir | Tablet 30 mg | Oral | Vocabria | C12619 | 30 | 0 |

**[5] Schedule 1, after entry for Cabotegravir**

*insert:*

| | | | | | | |
|---|---|---|---|---|---|---|
| Cabotegravir and rilpivirine | Pack containing 1 vial cabotegravir 600 mg in 3 mL and 1 vial rilpivirine 900 mg in 3mL | Injection | Cabenuva | C12636 | 1 | 5 |

**[6] Schedule 1, after entry for Efavirenz in the form Tablet 600 mg**

*insert:*

| | | | | | | |
|---|---|---|---|---|---|---|
| Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor | Pack containing 56 tablets elexacaftor 100 mg with tezacaftor 50 mg and with ivacaftor 75 mg and 28 tablets ivacaftor 150 mg | Oral | Trikafta | C12618 C12626 | See Schedule 2 | See Schedule 2 |

**[7] Schedule 1, entry for Ivacaftor in each of the forms: Sachet containing granules 50 mg; Sachet containing granules 75 mg; and Tablet 150 mg**

*omit from the column headed "Circumstances":* **C9889 C9890** *substitute:* **C12624 C12625**

**[8]** **Schedule 1, entry for Lumacaftor with ivacaftor in each of the forms: Sachet containing granules, lumacaftor 100 mg and ivacaftor 125 mg; and Sachet containing granules, lumacaftor 150 mg and ivacaftor 188 mg**

*omit from the column headed "Circumstances":* **C10005 C10007** *substitute:* **C12610 C12621**

**[9]** **Schedule 1, entry for Lumacaftor with ivacaftor in the form Tablet containing lumacaftor 100 mg with ivacaftor 125 mg**

*omit from the column headed "Circumstances":* **C9891 C9920** *substitute:* **C12627 C12633**

**[10]** **Schedule 1, entry for Lumacaftor with ivacaftor in the form Tablet containing lumacaftor 200 mg with ivacaftor 125 mg**

*omit from the column headed "Circumstances":* **C9857 C9943** *substitute:* **C12612 C12623**

**[11]** **Schedule 1, entry for Pegfilgrastim**

**(a)** *omit:*

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | Neulasta | C7822 C7843 C9235 C9303 | 1 | 11 |

**(b)** *omit:*

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | Tezmota | C7822 C7843 C9235 C9303 | 1 | 11 |

**[12]** **Schedule 1, entry for Ravulizumab in each of the forms: Solution concentrate for I.V. infusion 300 mg in 3 mL; and Solution concentrate for I.V. infusion 1,100 mg in 11 mL**

**(a)** *omit from the column headed "Circumstances":* **C12509**

**(b)** *omit from the column headed "Circumstances":* **C12575**

**(c)** *insert in numerical order in the column headed "Circumstances":* **C12593 C12605**

**[13]** **Schedule 1, after entry for Sildenafil**

*insert:*

| | | | | | | |
|---|---|---|---|---|---|---|
| Siltuximab | Powder for injection 100 mg | Injection | Sylvant | C12585 C12594 | 2 | 4 |
| | Powder for injection 400 mg | Injection | Sylvant | C12585 C12594 | 2 | 4 |

**[14]** **Schedule 1, entry for Tezacaftor with ivacaftor and ivacaftor**

*omit from the column headed "Circumstances":* **C9880 C9961 C10064 C10069** *substitute:* **C12609 C12614 C12630 C12635**

**[15] Schedule 2, after entry for Eculizumab**

*insert:*

| | | | |
|---|---|---|---|
| Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor | C12618 C12626 | 1 pack | 5 |

**[16] Schedule 2, entry for Ivacaftor**

*substitute:*

| | | | |
|---|---|---|---|
| Ivacaftor | C12624 C12625 | 1 pack | Sufficient for 24 weeks of treatment |

**[17] Schedule 2, entry for Lumacaftor with Ivacaftor**

*substitute:*

| | | | |
|---|---|---|---|
| Lumacaftor with Ivacaftor | C12610 C12612 C12621 C12623 C12627 C12633 | 1 pack | 5 |

**[18] Schedule 2, entry for Ravulizumab**

*substitute:*

| | | | |
|---|---|---|---|
| Ravulizumab | C12517 C12518 C12519 | 1 dose | 0 |
| | C12511 C12593 C12605 | 1 dose | 2 |

**[19] Schedule 2, entry for Tezacaftor with Ivacaftor and Ivacaftor**

*substitute:*

| | | | |
|---|---|---|---|
| Tezacaftor with Ivacaftor and Ivacaftor | C12609 C12614 C12630 C12635 | 1 pack | 5 |

**[20] Schedule 3, after entry for Bosentan**

*insert:*

| | | | | |
|---|---|---|---|---|
| Cabotegravir | C12619 | | HIV infection<br>Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months; AND<br>The treatment must be in combination with rilpivirine tablets; AND<br>Patient must intend to proceed to treatment with intramuscular administration of cabotegravir and rilpivirine. | Compliance with Authority Required procedures - Streamlined Authority Code 12619 |

## [21] Schedule 3, after entry for Cabotegravir

*insert:*

| | | | | |
|---|---|---|---|---|
| Cabotegravir and rilpivirine | C12636 | | HIV infection<br>Patient must have previously received PBS-subsidised therapy for this condition; AND<br>The treatment must be the sole PBS-subsidised therapy for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 12636 |

## [22] Schedule 3, after entry for Efavirenz

*insert:*

| | | | | |
|---|---|---|---|---|
| Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor | C12618 | | Cystic fibrosis<br>Initial treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.<br>Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene; AND<br>The treatment must be given concomitantly with standard therapy for this condition; AND<br>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug.<br>Patient must be 12 years of age or older.<br>The patient must be registered in the Australian Cystic Fibrosis Database Registry.<br>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Cystic Fibrosis elexacaftor, tezacaftor with ivacaftor Authority Application Supporting Information Form; and<br>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and<br>(4) details of the name of the molecular testing for the patient having at least one F508del mutation including: (i) name of the pathology report provider (ii) date of pathology report (iii) unique identifying number/code that links the pathology result to the individual patient. | Compliance with Written Authority Required procedures |
| | C12626 | | Cystic fibrosis<br>Continuing treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in | Compliance with Written Authority Required procedures |



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|---|---|---|---|---|
| | | | cystic fibrosis if attendance is not possible due to geographic isolation.<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be given concomitantly with standard therapy for this condition.<br>Patient must be 12 years of age or older.<br>This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Cystic Fibrosis elexacaftor, tezacaftor with ivacaftor Authority Application Supporting Information Form; and<br>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | |

**[23] Schedule 3, entry for Ivacaftor**

*substitute:*

| | | | | |
|---|---|---|---|---|
| Ivacaftor | C12624 | | Cystic fibrosis<br>Initial treatment - New patients<br>Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND<br>Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR<br>Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele; AND<br>Patient must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction; AND<br>The treatment must be given concomitantly with standard therapy for this condition.<br>Patient must be aged 12 months or older.<br>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.<br>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.<br>Ivacaftor is not PBS-subsidised for this condition as a sole therapy.<br>Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:<br>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort | Compliance with Written Authority Required procedures |

| | | | | |
|---|---|---|---|---|
| | | | Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin<br>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and<br>(3) details of the pathology report substantiating G551D mutation or other gating (class III) mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and<br>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics; and<br>(5) sweat chloride result. | |
| | C12625 | | Cystic fibrosis<br>Continuing treatment<br>Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit; AND<br>Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition; AND<br>Patient must not receive more than 24 weeks of treatment under this restriction; AND<br>The treatment must be given concomitantly with standard therapy for this condition.<br>Patient must be aged 12 months or older.<br>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.<br>Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.<br>Ivacaftor is not PBS-subsidised for this condition as a sole therapy.<br>Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:<br>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort<br>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin<br>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and<br>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | Compliance with Written Authority Required procedures |

## [24] Schedule 3, entry for Lumacaftor with ivacaftor

*substitute:*

| | | | | |
|---|---|---|---|---|
| Lumacaftor with ivacaftor | C12610 | | Cystic fibrosis<br>Continuing treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND<br>The treatment must be given concomitantly with standard therapy for this condition.<br>Patient must be 2 years of age or older.<br>Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:<br>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.<br>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.<br>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and<br>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | Compliance with Written Authority Required procedures |
| | C12612 | | Cystic fibrosis<br>Continuing treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be given concomitantly with standard therapy for this condition; AND<br>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.<br>Patient must be 12 years of age or older.<br>Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:<br>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.<br>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin. | Compliance with Written Authority Required procedures |

| | | | | |
|---|---|---|---|---|
| | | | Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and<br>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | |
| | C12621 | | Cystic fibrosis<br>Initial treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.<br>Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND<br>The treatment must be given concomitantly with standard therapy for this condition; AND<br>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.<br>Patient must be 2 years of age or older.<br>Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:<br>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.<br>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.<br>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and<br>(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and<br>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | Compliance with Written Authority Required procedures |
| | C12623 | | Cystic fibrosis<br>Initial treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.<br>Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND<br>The treatment must be given concomitantly with standard therapy for this condition; AND<br>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; AND | Compliance with Written Authority Required procedures |

| | | | | |
|---|---|---|---|---|
| | | | The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.<br>Patient must be 12 years of age or older.<br>Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:<br>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.<br>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.<br>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and<br>(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and<br>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | |
| | C12627 | | Cystic fibrosis<br>Initial treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.<br>Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND<br>The treatment must be given concomitantly with standard therapy for this condition; AND<br>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities; AND<br>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.<br>Patient must be aged between 6 and 11 years inclusive.<br>Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:<br>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.<br>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.<br>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and<br>(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and<br>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | Compliance with Written Authority Required procedures |

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| | C12633 | | Cystic fibrosis<br>Continuing treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND<br>The treatment must be given concomitantly with standard therapy for this condition.<br>Patient must be aged between 6 and 11 years inclusive.<br>Lumacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:<br>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort.<br>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin.<br>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and<br>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | Compliance with Written Authority Required procedures |

**[25] Schedule 3, entry for Ravulizumab**

**(a)** *omit:*

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| | C12509 | P12509 | Paroxysmal nocturnal haemoglobinuria (PNH)<br>First Continuing Treatment<br>Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment criteria; AND<br>The treatment must not be in combination with eculizumab.<br>Must be treated by a haematologist; OR<br>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.<br>Patient must be aged 18 years or over.<br>At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.<br>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:<br>(i) Haemoglobin (g/L)<br>(ii) Platelets (x109/L)<br>(iii) White Cell Count (x109/L) | Compliance with Written Authority Required procedures |

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| | | | (iv) Reticulocytes (x109/L)<br>(v) Neutrophils (x109/L)<br>(vi) Granulocyte clone size (%)<br>(vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory<br>(viii) Multiple of LDH , ULN | |

**(b)** *omit:*

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| | C12575 | P12575 | Paroxysmal nocturnal haemoglobinuria (PNH)<br>Subsequent Continuing Treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Switch' criteria; AND<br>Patient must have demonstrated clinical improvement or stabilisation of condition; AND<br>The treatment must not be in combination with eculizumab.<br>Must be treated by a haematologist; OR<br>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.<br>Patient must be aged 18 years or over.<br>At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested. | Compliance with Written Authority Required procedures |

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

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| | C12593 | | Paroxysmal nocturnal haemoglobinuria (PNH)<br>First Continuing Treatment<br>Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial' or 'Grandfather' treatment criteria; AND<br>The treatment must not be in combination with eculizumab.<br>Must be treated by a haematologist; OR<br>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.<br>Patient must be aged 18 years or over.<br>At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.<br>At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:<br>(i) Haemoglobin (g/L)<br>(ii) Platelets ($x10^9$/L)<br>(iii) White Cell Count ($x10^9$/L)<br>(iv) Reticulocytes ($x10^9$/L)<br>(v) Neutrophils ($x10^9$/L)<br>(vi) Granulocyte clone size (%) | Compliance with Written Authority Required procedures |

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| | | | (vii) Lactate Dehydrogenase (LDH) and the upper limit of normal (ULN) for the reporting laboratory<br>(viii) Multiple of LDH , ULN | |
| | C12605 | | Paroxysmal nocturnal haemoglobinuria (PNH)<br>Subsequent Continuing Treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria; AND<br>Patient must have demonstrated clinical improvement or stabilisation of condition; AND<br>The treatment must not be in combination with eculizumab.<br>Must be treated by a haematologist; OR<br>Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.<br>Patient must be aged 18 years or over.<br>At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested. | Compliance with Written Authority Required procedures |

**[26] Schedule 3, after entry for Sildenafil**

*insert:*

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| Siltuximab | C12585 | | Idiopathic multicentric Castleman disease (iMCD)<br>Initial treatment<br>Patient must have a diagnosis of iMCD consistent with the latest international, evidence-based consensus diagnostic criteria for this condition with the relevant diagnostic findings documented in the patient's medical records; AND<br>The condition must not be, to the prescriber's best knowledge, any of the following diseases that can mimic iMCD: (i) human herpes virus-8 infection, (ii) an Epstein-Barr virus-lymphoproliferative disorder, (iii) an acute/uncontrolled infection (e.g. cytomegalovirus, toxoplasmosis, human immunodeficiency virus, tuberculosis) leading to inflammation with adenopathy, (iv) an autoimmune/autoinflammatory disease, (v) a malignant/lymphoproliferative disorder.<br>Must be treated by a haematologist; OR<br>Must be treated by a medical physician working under the supervision of a haematologist; AND<br>Patient must be undergoing treatment through this treatment phase once only in a lifetime, where the full number of repeats are prescribed; OR<br>Patient must be undergoing treatment through this treatment phase for up to the first 5 doses in a lifetime, where the full number of repeats was not prescribed with the first prescription.<br>Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum. | Compliance with Authority Required procedures |
| | C12594 | | Idiopathic multicentric Castleman disease (iMCD)<br>Continuing treatment<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition. | Compliance with Authority Required procedures |

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| | | | Must be treated by a haematologist; OR<br>Must be treated by a medical physician working under the supervision of a haematologist.<br>Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum. | |

**[27] Schedule 3, entry for Tezacaftor with ivacaftor and ivacaftor**

*substitute:*

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| Tezacaftor with ivacaftor and ivacaftor | C12609 | | Cystic fibrosis - one residual function (RF) mutation<br>Continuing treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND<br>The treatment must be given concomitantly with standard therapy for this condition.<br>Patient must be 12 years of age or older.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.<br>Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:<br>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;<br>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;<br>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and<br>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | Compliance with Written Authority Required procedures |
| | C12614 | | Cystic fibrosis - homozygous for the F508del mutation<br>Continuing treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic | Compliance with Written Authority Required procedures |



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| | | | isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.<br>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND<br>The treatment must be given concomitantly with standard therapy for this condition.<br>Patient must be 12 years of age or older.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.<br>Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:<br>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;<br>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;<br>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and<br>(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | |
| | C12630 | | Cystic fibrosis - one residual function (RF) mutation<br>Initial treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.<br>Patient must have at least one residual function (RF) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor with ivacaftor; AND<br>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND<br>The treatment must be given concomitantly with standard therapy for this condition; AND<br>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.<br>Patient must be 12 years of age or older.<br>For the purposes of this restriction, the list of mutations considered to be responsive to tezacaftor with ivacaftor is defined in the TGA approved product information.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on | Compliance with Written Authority Required procedures |

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| | | | alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.<br>Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:<br>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;<br>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;<br>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and<br>(3) details of the pathology report substantiating the patient having at least one RF mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient ; and<br>(4) CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | |
| | C12635 | | Cystic fibrosis - homozygous for the F508del mutation<br>Initial treatment<br>Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation; AND<br>Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.<br>Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; AND<br>The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition; AND<br>The treatment must be given concomitantly with standard therapy for this condition; AND<br>Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.<br>Patient must be 12 years of age or older.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.<br>Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.<br>Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of | Compliance with Written Authority Required procedures |

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| | | | the following CYP3A4 inducers:<br>Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;<br>Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;<br>Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.<br>The authority application must be in writing and must include:<br>(1) a completed authority prescription; and<br>(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and<br>(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and<br>(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics. | |