

**PB 59 of 2022**

National Health (Continued Dispensing) Determination 2022

I, David Laffan, as delegate of the Minister for Health and Aged Care, make the following determination.

Dated 28 June 2022

David Laffan

Assistant Secretary
Pharmacy Branch
Technology Assessment and Access Division
Department of Health

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Part 1—Preliminary

1.01 Name

 (1) This instrument is the *National Health (Continued Dispensing) Determination 2022*.

 (2) This instrument may also be cited as PB 59 of 2022.

1.02 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 July 2022. | 1 July 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Note: This table relates only to the provisions of this instrument as originally made.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.

1.03 Authority

 This instrument is made under subsection 89A(3) of the *National Health Act 1953*.

1.04 Schedule 2

 Each instrument that is specified in Schedule 2 to this instrument is amended or repealed as set out in the applicable items in that Schedule, and any other item in that Schedule has effect according to its terms.

1.05 Definitions

 (1) In this instrument:

***Act*** means the *National Health Act 1953*.

***electronic prescription*** has the meaning given by subsection 5(1) of the Regulations.

***patient***: see subsection 3.01(1).

***Regulations*** means the *National Health (Pharmaceutical Benefits) Regulations 2017*.

***requested supply***: see subsection 3.01(1).

 (2) An expression that is used in this instrument and in Part VII of the Act has the same meaning in this instrument as it has in that Part.

Examples:

(a) approved pharmacist;

(b) listed brand;

(c) PBS prescriber;

(d) pharmaceutical benefit;

(e) pharmaceutical item;

(f) Schedule equivalent.

1.06 Purpose

 The purpose of this instrument is to determine:

 (a) the pharmaceutical benefits that may be supplied by an approved pharmacist without a prescription; and

 (b) the conditions that must be satisfied when making a supply of those pharmaceutical benefits.

Part 2—Pharmaceutical benefits that may be supplied without a prescription

2.01 Pharmaceutical benefits covered by this instrument

 For the purposes of paragraph 89A(3)(a) of the Act, the pharmaceutical benefits covered by an item in the table in Schedule 1 (being the listed drugs specified in the item) are determined to be pharmaceutical benefits that may be supplied by an approved pharmacist without a prescription.

Part 3—Specified conditions for supplying pharmaceutical benefits without a prescription

3.01 General

 (1) For the purposes of paragraph 89A(3)(b) of the Act, the conditions specified in this Part are determined to be the conditions that must be satisfied when making a supply (the ***requested supply***) of a pharmaceutical benefit to a person (the ***patient***) requesting the supply without a prescription in accordance with subsection 89A(1) of the Act.

 (2) In this Part:

 (a) a reference to the PBS prescriber is a reference to the PBS prescriber who most recently prescribed the supply of the pharmaceutical benefit to the patient; and

 (b) a reference to “the pharmaceutical benefit” in sections 3.03, 3.05, 3.06 and 3.07 includes a reference to a pharmaceutical benefit that is a Schedule equivalent.

3.02 Condition—unable to obtain prescription

 The approved pharmacist must be satisfied of either or both of the following:

 (a) the PBS prescriber is unable to be contacted;

 (b) the PBS prescriber is unable to provide an electronic prescription.

3.03 Condition—previous supply of pharmaceutical benefit

 The approved pharmacist must be satisfied that:

 (a) the patient has previously been supplied the pharmaceutical benefit on the basis of a prescription from a PBS prescriber; and

 (b) the PBS prescriber prescribed the supply of the pharmaceutical benefit for the patient in at least one of the circumstances determined for that pharmaceutical benefit under paragraph 85(7)(b) of the Act.

Note: The circumstances determined under paragraph 85(7)(b) of the Act relate to pharmaceutical benefits that are relevant pharmaceutical benefits under section 88A of the Act.

3.04 Condition—stability of therapy

 The approved pharmacist must be satisfied that the patient’s therapy is stable.

3.05 Condition—prior clinical review by PBS prescriber

 The approved pharmacist must be satisfied that:

 (a) the patient has been taking the pharmaceutical benefit regularly for an uninterrupted period; and

 (b) since the start of that period, the PBS prescriber has assessed the patient’s condition and decided that there is a need for ongoing treatment with the pharmaceutical benefit.

Note: See paragraph 3.01(2)(a) for references to the PBS prescriber.

3.06 Condition—prescription for last supply of pharmaceutical benefit

 The approved pharmacist must be satisfied that the patient had a valid prescription under Part VII of the Act for the last supply of the pharmaceutical benefit to the patient before the requested supply.

3.07 Condition—no continued dispensing in previous 12 months

 The approved pharmacist must be satisfied that the patient was not supplied with the pharmaceutical benefit under subsection 89A(1) of the Act in the 12 months before the requested supply.

3.08 Condition—declaration for supply of pharmaceutical benefit

 The approved pharmacist must ensure that the patient, or an agent of the patient (other than the approved pharmacist), signs a declaration acknowledging that the patient is being supplied with the pharmaceutical benefit without the presentation of a valid prescription under Part VII of the Act.

3.09 Condition—maximum quantity of supply

 The approved pharmacist must supply a maximum quantity or number of units of the pharmaceutical item in the pharmaceutical benefit determined under paragraph 85A(2)(a) of the Act.

3.10 Condition—preparing and recording information

 (1) The approved pharmacist must, when the pharmaceutical benefit is supplied:

 (a) record the information that the pharmacist used to support the pharmacist’s decision to supply the pharmaceutical benefit; and

 (b) prepare information about the supply to the patient that the pharmacist will send to the PBS prescriber.

 (2) The information that must be recorded and prepared under subsection (1) must include the following:

 (a) a statement that the pharmaceutical benefit supplied is a pharmaceutical benefit covered by Schedule 1;

 (b) a statement that the conditions mentioned in sections 3.02 to 3.05 are satisfied;

 (c) a statement that the approved pharmacist is satisfied that the pharmaceutical benefit needs to be supplied to the patient to facilitate continuity of treatment.

Part 4—Application, savings and transitional provisions

4.01 Application of this instrument

 Despite the repeal of the *National Health (Continued Dispensing – Emergency Measures) Determination 2020*, that instrument (the ***emergency instrument***) continues to have effect, on and after 1 July 2022, for the purposes of the *National Health (Supply of Pharmaceutical Benefits—Under Co‑payment Data and Claims for Payment) Rules 2022* in relation to a supply of a pharmaceutical benefit made in accordance with the emergency instrument on or before 30 June 2022 as if the repeal had not happened.

Schedule 1—Pharmaceutical benefits that may be supplied without a prescription

Note: See section 3.01.

1 Pharmaceutical benefits that may be supplied without a prescription by an approved pharmacist

| Item | Listed drug |
| --- | --- |
| 1 | Abacavir |
| 2 | Abacavir with lamivudine |
| 3 | Abacavir with lamivudine and zidovudine |
| 4 | Acarbose |
| 5 | Adefovir |
| 6 | Alogliptin |
| 7 | Alogliptin with metformin |
| 8 | Amiloride with hydrochlorothiazide |
| 9 | Amlodipine |
| 10 | Amlodipine with atorvastatin |
| 11 | Amlodipine with valsartan |
| 12 | Amlodipine with valsartan and hydrochlorothiazide |
| 13 | Atazanavir |
| 14 | Atazanavir with cobicistat |
| 15 | Atenolol |
| 16 | Atorvastatin |
| 17 | Beclometasone |
| 18 | Beclometasone with Formoterol (eformoterol) |
| 19 | Bictegravir with emtricitabine with tenofovir alafenamide |
| 20 | Bisoprolol |
| 21 | Budesonide |
| 22 | Budesonide with Formoterol (eformoterol) |
| 23 | Candesartan |
| 24 | Candesartan with hydrochlorothiazide |
| 25 | Captopril |
| 26 | Carvedilol |
| 27 | Chlortalidone |
| 28 | Ciclesonide |
| 29 | Cromoglycate |
| 30 | Dapagliflozin |
| 31 | Dapagliflozin with metformin |
| 32 | Darunavir |
| 33 | Darunavir with cobicistat |
| 34 | Darunavir with cobicistat, emtricitabine and tenofovir alafenamide |
| 35 | Diltiazem |
| 36 | Dolutegravir |
| 37 | Dolutegravir with abacavir and lamivudine |
| 38 | Dolutegravir with lamivudine |
| 39 | Dolutegravir with rilpivirine |
| 40 | Dulaglutide |
| 41 | Efavirenz |
| 42 | Empagliflozin |
| 43 | Empagliflozin with linagliptin |
| 44 | Empagliflozin with metformin |
| 45 | Emtricitabine with rilpivirine with tenofovir alafenamide |
| 46 | Emtricitabine with tenofovir alafenamide |
| 47 | Enalapril |
| 48 | Enalapril with hydrochlorothiazide |
| 49 | Enfuvirtide |
| 50 | Entecavir |
| 51 | Eplerenone |
| 52 | Eprosartan |
| 53 | Eprosartan with hydrochlorothiazide |
| 54 | Ertugliflozin |
| 55 | Ertugliflozin with metformin |
| 56 | Ertugliflozin with sitagliptin |
| 57 | Etacrynic acid |
| 58 | Etravirine |
| 59 | Exenatide |
| 60 | Ezetimibe with atorvastatin |
| 61 | Ezetimibe with rosuvastatin |
| 62 | Ezetimibe with simvastatin |
| 63 | Felodipine |
| 64 | Fluticasone furoate |
| 65 | Fluticasone furoate with Vilanterol |
| 66 | Fluticasone propionate |
| 67 | Fluticasone propionate with Formoterol (eformoterol) |
| 68 | Fluticasone propionate with Salmeterol |
| 69 | Fluvastatin |
| 70 | Formoterol (eformoterol) |
| 71 | Fosamprenavir |
| 72 | Fosinopril |
| 73 | Fosinopril with hydrochlorothiazide |
| 74 | Furosemide (frusemide) |
| 75 | Glibenclamide |
| 76 | Gliclazide |
| 77 | Glimepiride |
| 78 | Glipizide |
| 79 | Hydrochlorothiazide |
| 80 | Indacaterol |
| 81 | Indacaterol with Mometasone |
| 82 | Indapamide |
| 83 | Insulin aspart |
| 84 | Insulin aspart with insulin aspart protamine |
| 85 | Insulin degludec with insulin aspart |
| 86 | Insulin detemir |
| 87 | Insulin glargine |
| 88 | Insulin glulisine |
| 89 | Insulin isophane human |
| 90 | Insulin isophane human with insulin neutral human |
| 91 | Insulin lispro |
| 92 | Insulin lispro with insulin lispro protamine |
| 93 | Insulin neutral human |
| 94 | Irbesartan |
| 95 | Irbesartan with hydrochlorothiazide |
| 96 | Labetalol |
| 97 | Lamivudine |
| 98 | Lamivudine with zidovudine |
| 99 | Lercanidipine |
| 100 | Lercanidipine with enalapril |
| 101 | Levonorgestrel |
| 102 | Levonorgestrel with ethinylestradiol |
| 103 | Linagliptin |
| 104 | Linagliptin with metformin |
| 105 | Lisinopril |
| 106 | Lopinavir with ritronavir |
| 107 | Losartan |
| 108 | Maraviroc |
| 109 | Metformin |
| 110 | Metformin with glibenclamide |
| 111 | Metoprolol succinate |
| 112 | Metoprolol tartrate |
| 113 | Nebivolol |
| 114 | Nedocromil |
| 115 | Nevirapine |
| 116 | Nifedipine |
| 117 | Norethisterone |
| 118 | Norethisterone with ethinylestradiol |
| 119 | Norethisterone with Mestranol |
| 120 | Olmesartan |
| 121 | Olmesartan with amlodipine and hydrochlorothiazide |
| 122 | Olmesartan with hydrochlorothiazide |
| 123 | Olmesartan medoxomil with amlodipine |
| 124 | Oxprenolol |
| 125 | Perindopril |
| 126 | Perindopril with amlodipine |
| 127 | Perindopril with indapamide |
| 128 | Pindolol |
| 129 | Pioglitazone |
| 130 | Pravastatin |
| 131 | Propranolol |
| 132 | Quinapril |
| 133 | Quinapril with hydrochlorothiazide |
| 134 | Raltegravir |
| 135 | Ramipril |
| 136 | Ramipril with felodipine |
| 137 | Rilpivirine |
| 138 | Ritonavir |
| 139 | Rosuvastatin |
| 140 | Sacubitril with valsartan |
| 141 | Salbutamol |
| 142 | Salmeterol |
| 143 | Saquinavir |
| 144 | Saxagliptin |
| 145 | Saxagliptin with dapagliflozin |
| 146 | Saxagliptin with metformin |
| 147 | Semaglutide |
| 148 | Simvastatin |
| 149 | Sitagliptin |
| 150 | Sitagliptin with metformin |
| 151 | Spironolactone |
| 152 | Telmisartan |
| 153 | Telmisartan with amlodipine |
| 154 | Telmisartan with hydrochlorothiazide |
| 155 | Tenofovir with emtricitabine |
| 156 | Tenofovir with emtricitabine and efavirenz |
| 157 | Tenofovir alafenamide with emtricitabine, elvitegravir and cobicistat |
| 158 | Tenofovir disoproxil |
| 159 | Terbutaline |
| 160 | Tipranavir |
| 161 | Trandolapril |
| 162 | Trandolapril with verapamil |
| 163 | Valsartan |
| 164 | Valsartan with hydrochlorothiazide |
| 165 | Verapamil |
| 166 | Vildagliptin |
| 167 | Vildagliptin with metformin |
| 168 | Zidovudine |

Schedule 2—Repeals

National Health (Continued Dispensing) Determination 2012

1 The whole of the instrument

Repeal the instrument.

National Health (Continued Dispensing – Emergency Measures) Determination 2020

2 The whole of the instrument

Repeal the instrument.