



**PB 32 of 2020**

# **National Health (Pharmaceutical Benefits) Legislation Amendment (Continuing Treatment during Coronavirus Pandemic) Instrument 2020**

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I, Thea Daniel, as delegate of the Minister for Health, make the following instrument.

Dated 29 April 2020

Thea Daniel  
Assistant Secretary  
Pricing and PBS Policy Branch  
Technology Assessment and Access Division  
Department of Health

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## Contents

1	Name.....	1
2	Commencement .....	1
3	Authority.....	1
4	Schedules .....	1
<b>Schedule 1—Amendments</b>		<b>2</b>
Part 1—Amendments of main listing instrument		2
<i>National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (PB 71 of 2012)</i>		2
Part 2—Amendments of special arrangement		7
<i>National Health (Highly specialised drugs program) Special Arrangement 2010 (PB 116 of 2010)</i>		7



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## 1 Name

- (1) This instrument is the *National Health (Pharmaceutical Benefits) Legislation Amendment (Continuing Treatment during Coronavirus Pandemic) Instrument 2020*.
- (2) This instrument may also be cited as PB 32 of 2020.

## 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 May 2020.	1 May 2020

Note: This table relates only to the provisions of this instrument as originally made.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

- (a) subsection 85(7) of the *National Health Act 1953*;
- (b) 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

### Part 1—Amendments of main listing instrument

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

##### 1 After subsection 10(3)

Insert:

- (3A) Subsection (3) has effect subject to section 10A (which temporarily modifies the circumstances mentioned in Part 1 of Schedule 4 for circumstances codes for pharmaceutical benefits that are pharmaceutical items described in Schedule 6).

##### 2 After section 10

Insert:

#### 10A Modified prescription circumstances during COVID-19 pandemic

- (1) This section affects the circumstances in which a prescription may be written by an authorised prescriber for the supply of a pharmaceutical benefit that is a listed brand of a pharmaceutical item described in Schedule 6 to a person (the *patient*) if the authorised prescriber is satisfied the patient has, in accordance with Part VII of the Act, already been supplied with the benefit on the basis of a prescription written in circumstances determined by subsection 10(3) unaffected by this section.
- (2) For the purposes of subsection 10(3), Part 1 of Schedule 4 has effect as if each circumstances code for the pharmaceutical benefit:
- (a) did not mention any circumstance that, having regard to the patient's situation and the state of affairs associated with precautions against the spread of the coronavirus known as COVID-19, it is not reasonably practicable to establish in relation to the patient; and
  - (b) mentioned the circumstance that the authorised prescriber keeps a written record of the reason it is not practicable to establish the circumstance described in paragraph (a).
- (3) This section, subsection 10(3A) and Schedule 6 are repealed at the start of 1 October 2020.

##### 3 At the end of the instrument

Add:

## Schedule 6—Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic

Note: See section 10A.

<b>Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic</b>			
<b>Item</b>	<b>Column 1 Listed drug</b>	<b>Column 2 Form</b>	<b>Column 3 Manner of administration</b>
1	Abatacept	Injection 125 mg in 1 mL single dose autoinjector,	Injection
2	Abatacept	Injection 125 mg in 1 mL single dose pre-filled syringe	Injection
3	Abatacept	Powder for I.V. infusion 250 mg	Injection
4	Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection
5	Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection
6	Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe, 6	Injection
7	Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection
8	Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen, 4	Injection
9	Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen, 6	Injection
10	Ambrisentan	Tablet 5 mg	Oral
11	Ambrisentan	Tablet 10 mg	Oral
12	Baricitinib	Tablet 2 mg	Oral
13	Baricitinib	Tablet 4 mg	Oral
14	Benralizumab	Injection 30 mg in 1 mL single dose pre-filled syringe	Injection
15	Benralizumab	Injection 30 mg in 1 mL single dose pre-filled pen	Injection
16	Bosentan	Tablet 62.5 mg (as monohydrate)	Oral
17	Bosentan	Tablet 125 mg (as monohydrate)	Oral
18	Certolizumab pegol	Injection 200 mg in 1 mL single use pre-filled syringe	Injection
19	Certolizumab pegol	Solution for injection 200 mg in 1 mL pre-filled pen	Injection
20	Dornase alfa	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	Inhalation
21	Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium)	Injection
22	Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL	Injection
23	Epoprostenol	Powder for I.V. infusion 1.5 mg (as sodium)	Injection
24	Epoprostenol	Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL	Injection
25	Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection
26	Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection
27	Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection
28	Golimumab	Injection 50 mg in 0.5 mL single use pre-filled pen	Injection
29	Golimumab	Injection 50 mg in 0.5 mL single use pre-filled syringe	Injection
30	Golimumab	Injection 100 mg in 1 mL single use pre-filled pen	Injection
31	Guselkumab	Injection 100 mg in 1 mL single use pre-filled syringe	Injection

**Schedule 1** Amendments**Part 1** Amendments of main listing instrument

<b>Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic</b>			
<b>Item</b>	<b>Column 1 Listed drug</b>	<b>Column 2 Form</b>	<b>Column 3 Manner of administration</b>
32	Iloprost	Solution for inhalation 20 micrograms (as trometamol) in 2 mL	Inhalation
33	Infliximab	Powder for I.V. infusion 100 mg	Injection
34	Ivacaftor	Sachet containing granules 50 mg	Oral
35	Ivacaftor	Sachet containing granules 75 mg	Oral
36	Ivacaftor	Tablet 150 mg	Oral
37	Ixekizumab	Injection 80 mg in 1 mL single dose pre-filled pen	Injection
38	Lenalidomide	Capsule 5 mg	Oral
39	Lenalidomide	Capsule 10 mg	Oral
40	Lenalidomide	Capsule 15 mg	Oral
41	Lenalidomide	Capsule 25 mg	Oral
42	Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 100 mg and ivacaftor 125 mg	Oral
43	Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 150 mg and ivacaftor 188 mg	Oral
44	Lumacaftor with ivacaftor	Tablet containing lumacaftor 100 mg with ivacaftor 125 mg	Oral
45	Lumacaftor with ivacaftor	Tablet containing lumacaftor 200 mg with ivacaftor 125 mg	Oral
46	Macitentan	Tablet 10 mg	Oral
47	Mannitol	Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers	Inhalation by mouth
48	Mepolizumab	Powder for injection 100 mg	Injection
49	Montelukast	Tablet, chewable, 4 mg (as sodium)	Oral
50	Montelukast	Tablet, chewable, 5 mg (as sodium)	Oral
51	Nintedanib	Capsule 100 mg	Oral
52	Nintedanib	Capsule 150 mg	Oral
53	Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection
54	Omalizumab	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection
55	Pirfenidone	Capsule 267 mg	Oral
56	Pirfenidone	Tablet 267 mg	Oral
57	Pirfenidone	Tablet 801mg	Oral
58	Pomalidomide	Capsule 3 mg	Oral
59	Pomalidomide	Capsule 4 mg	Oral
60	Riociguat	Tablet 500 micrograms	Oral
61	Riociguat	Tablet 1 mg	Oral
62	Riociguat	Tablet 1.5 mg	Oral
63	Riociguat	Tablet 2 mg	Oral
64	Riociguat	Tablet 2.5 mg	Oral



<b>Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic</b>			
<b>Item</b>	<b>Column 1 Listed drug</b>	<b>Column 2 Form</b>	<b>Column 3 Manner of administration</b>
65	Risankizumab	Injection 75 mg in 0.83 mL pre-filled syringe	Injection
66	Rituximab	Solution for I.V. infusion 500 mg in 50 mL	Injection
67	Secukinumab	Injection 150 mg in 1 mL pre-filled pen	Injection
68	Sildenafil	Tablet 20 mg (as citrate)	Oral
69	Somatropin	Injection 0.4 mg (1.2 i.u.) with diluent in single use syringe (without preservative)	Injection
70	Somatropin	Injection 0.6 mg (1.8 i.u.) with diluent in single use syringe (without preservative)	Injection
71	Somatropin	Injection 0.8 mg (2.4 i.u.) with diluent in single use syringe (without preservative)	Injection
72	Somatropin	Injection 1 mg (3 i.u.) with diluent in single use syringe (without preservative)	Injection
73	Somatropin	Injection 1.2 mg (3.6 i.u.) with diluent in single use syringe (without preservative)	Injection
74	Somatropin	Injection 1.4 mg (4.2 i.u.) with diluent in single use syringe (without preservative)	Injection
75	Somatropin	Injection 1.6 mg (4.8 i.u.) with diluent in single use syringe (without preservative)	Injection
76	Somatropin	Injection 1.8 mg (5.4 i.u.) with diluent in single use syringe (without preservative)	Injection
77	Somatropin	Injection 2 mg (6 i.u.) with diluent in single use syringe (without preservative)	Injection
78	Somatropin	Injection 4 mg (12 i.u.) vial with diluent (with preservative)	Injection
79	Somatropin	Injection 18 i.u. (6 mg) cartridge with 3.15 mL diluent (with preservative)	Injection
80	Somatropin	Injection 72 i.u. (24 mg) cartridge with 3.15 mL diluent (with preservative)	Injection
81	Somatropin	Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative)	Injection
82	Somatropin	Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative)	Injection
83	Somatropin	Injection 36 i.u. (12 mg) cartridge with 3.15 mL diluent (with preservative)	Injection
84	Somatropin	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen	Injection
85	Somatropin	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)	Injection
86	Somatropin	Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative)	Injection
87	Somatropin	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)	Injection
88	Somatropin	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen	Injection

**Schedule 1** Amendments**Part 1** Amendments of main listing instrument

<b>Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic</b>			
<b>Item</b>	<b>Column 1 Listed drug</b>	<b>Column 2 Form</b>	<b>Column 3 Manner of administration</b>
89	Somatropin	Solution for injection 10 mg (30 i.u.) in 2 mL cartridge (with preservative)	Injection
90	Somatropin	Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative)	Injection
91	Somatropin	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)	Injection
92	Somatropin	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen	Injection
93	Somatropin	Solution for injection 20 mg (60 i.u.) in 2.5 mL cartridge (with preservative)	Injection
94	Tadalafil	Tablet 20 mg	Oral
95	Tezacaftor with ivacaftor and ivacaftor	Pack containing 28 tablets tezacaftor 100 mg with ivacaftor 150 mg and 28 tablets ivacaftor 150 mg	Oral
96	Tildrakizumab	Injection 100 mg in 1 mL single dose pre-filled syringe	Injection
97	Tocilizumab	Concentrate for injection 80 mg in 4 mL	Injection
98	Tocilizumab	Concentrate for injection 200 mg in 10 mL	Injection
99	Tocilizumab	Concentrate for injection 400 mg in 20 mL	Injection
100	Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled pen	Injection
101	Tocilizumab	Injection 162 mg in 0.9 mL single use pre-filled syringe	Injection
102	Tofacitinib	Tablet 5 mg	Oral
103	Ustekinumab	Injection 45 mg in 0.5 mL	Injection
104	Ustekinumab	Solution for I.V. infusion 130 mg in 26 mL	Injection
105	Vedolizumab	Powder for injection 300 mg	Injection

## **Part 2—Amendments of special arrangement**

### ***National Health (Highly specialised drugs program) Special Arrangement 2010 (PB 116 of 2010)***

#### **4 At the end of section 9**

Add:

- (3) This section has effect subject to section 9AA (which temporarily modifies the circumstances mentioned in Schedule 3 for circumstances codes for HSD pharmaceutical benefits that are pharmaceutical items described in Schedule 5).

#### **5 After section 9**

Insert:

#### **9AA Modified prescription circumstances during COVID-19 pandemic**

- (1) This section affects the circumstances in which a prescription may be written by an authorised prescriber for the supply of an HSD pharmaceutical benefit that is a listed brand of a pharmaceutical item described in Schedule 5 to a person (the *patient*) if the authorised prescriber is satisfied the patient has, in accordance with this Special Arrangement, already been supplied with the benefit on the basis of a prescription written in circumstances determined by subsection 9(1) unaffected by this section.
- (2) For the purposes of subsection 9(1), Schedule 3 has effect as if each circumstances code for the HSD pharmaceutical benefit:
  - (a) did not mention any circumstance that, having regard to the patient's situation and the state of affairs associated with precautions against the spread of the coronavirus known as COVID-19, it is not reasonably practicable to establish in relation to the patient; and
  - (b) mentioned the circumstance that the authorised prescriber keeps a written record of the reason it is not practicable to establish the circumstance described in paragraph (a).
- (3) This section, subsection 9(3) and Schedule 5 are repealed at the start of 1 October 2020.

#### **6 At the end of the instrument**

Add:

### **Schedule 5—HSD pharmaceutical benefits with modified prescription circumstances during COVID-19 pandemic**

Note: See section 9AA.

**Schedule 1** Amendments

**Part 2** Amendments of special arrangement

<b>Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic</b>			
<b>Item</b>	<b>Column 1 Listed drug</b>	<b>Column 2 Form</b>	<b>Column 3 Manner of administration</b>
1	Abatacept	Powder for I.V. infusion 250 mg	Injection
2	Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection
3	Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection
4	Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection
5	Ambrisentan	Tablet 5 mg	Oral
6	Ambrisentan	Tablet 10 mg	Oral
7	Benralizumab	Injection 30 mg in 1 mL single dose pre-filled syringe	Injection
8	Benralizumab	Injection 30 mg in 1 mL single dose pre-filled pen	Injection
9	Bosentan	Tablet 62.5 mg (as monohydrate)	Oral
10	Bosentan	Tablet 125 mg (as monohydrate)	Oral
11	Dornase alfa	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	Inhalation
12	Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium)	Injection
13	Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL	Injection
14	Epoprostenol	Powder for I.V. infusion 1.5 mg (as sodium)	Injection
15	Epoprostenol	Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL	Injection
16	Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection
17	Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection
18	Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection
19	Iloprost	Solution for inhalation 20 micrograms (as trometamol) in 2 mL	Inhalation
20	Infliximab	Powder for I.V. infusion 100 mg	Injection
21	Ivacaftor	Sachet containing granules 50 mg	Oral
22	Ivacaftor	Sachet containing granules 75 mg	Oral
23	Ivacaftor	Tablet 150 mg	Oral
24	Lenalidomide	Capsule 5 mg	Oral
25	Lenalidomide	Capsule 10 mg	Oral
26	Lenalidomide	Capsule 15 mg	Oral
27	Lenalidomide	Capsule 25 mg	Oral
28	Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 100 mg and ivacaftor 125 mg	Oral
29	Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 150 mg and ivacaftor 188 mg	Oral
30	Lumacaftor with ivacaftor	Tablet containing lumacaftor 100 mg with ivacaftor 125 mg	Oral
31	Lumacaftor with ivacaftor	Tablet containing lumacaftor 200 mg with ivacaftor 125 mg	Oral

<b>Pharmaceutical items with modified prescription circumstances during COVID-19 pandemic</b>			
<b>Item</b>	<b>Column 1 Listed drug</b>	<b>Column 2 Form</b>	<b>Column 3 Manner of administration</b>
32	Macitentan	Tablet 10 mg	Oral
33	Mannitol	Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers	Inhalation by mouth
34	Mepolizumab	Powder for injection 100 mg	Injection
35	Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection
36	Omalizumab	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection
37	Pomalidomide	Capsule 3 mg	Oral
38	Pomalidomide	Capsule 4 mg	Oral
39	Riociguat	Tablet 500 micrograms	Oral
40	Riociguat	Tablet 1 mg	Oral
41	Riociguat	Tablet 1.5 mg	Oral
42	Riociguat	Tablet 2 mg	Oral
43	Riociguat	Tablet 2.5 mg	Oral
44	Rituximab	Solution for I.V. infusion 500 mg in 50 mL	Injection
45	Sildenafil	Tablet 20 mg (as citrate)	Oral
46	Tadalafil	Tablet 20 mg	Oral
47	Tezacaftor with ivacaftor and ivacaftor	Pack containing 28 tablets tezacaftor 100 mg with ivacaftor 150 mg and 28 tablets ivacaftor 150 mg	Oral
48	Tocilizumab	Concentrate for injection 80 mg in 4 mL	Injection
49	Tocilizumab	Concentrate for injection 200 mg in 10 mL	Injection
50	Tocilizumab	Concentrate for injection 400 mg in 20 mL	Injection
51	Ustekinumab	Solution for I.V. infusion 130 mg in 26 mL	Injection
52	Vedolizumab	Powder for injection 300 mg	Injection