



**PB 46 of 2020**

# **National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2020 (No. 5)**

*National Health Act 1953*

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

Dated            29 May 2020

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

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## **1 Name of Instrument**

- (1) This Instrument is the *National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2020 (No. 5)*.
- (2) This Instrument may also be cited as PB 46 of 2020.

## **2 Commencement**

This Instrument commences on 1 June 2020.

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

Schedule 1 amends the *National Health (Highly specialised drugs program) Special Arrangement 2010 (PB 116 of 2010)*.

## Schedule 1 Amendments

**[1] Part 1, Division 1, Section 4, definition for ‘CAR drug’**

*omit:* ambristentan      *substitute:* ambrisentan

**[2] Schedule 1, entry for Lenalidomide in each of the forms: Capsule 5 mg; Capsule 10 mg; Capsule 15 mg; and Capsule 25 mg**

(a) *omit from the column headed “Circumstances”:* **C10421**

(b) *insert in numerical order in the column headed “Circumstances”:* **C10427 C10428 C10429 C10452 C10453**

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

*insert as first entry:*

Injection 100 mg in 1 mL single dose pre-filled pen	Injection	Nucala	GK	C9885 C10221 C10222 C10280 C10483 C10484	P9885	1	0	D
				C9885 C10221 C10222 C10280 C10483 C10484	P10280 P10483 P10484	1	5	D
				C9885 C10221 C10222 C10280 C10483 C10484	P10221 P10222	1	7	D

**[4] Schedule 1, entry for Sevelamer in the form Tablet containing sevelamer carbonate 800 mg**

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

	Sevelamer Lupin	GQ	C5530 C9762	360	5	C
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**[5] Schedule 3, entry for Lenalidomide**

(a) *omit:*

C10421	Multiple myeloma Continuing treatment until progression in patients treated with dual combination therapy (lenalidomide and dexamethasone) Patient must have previously been authorised with a PBS prescription with this drug for the condition; AND Patient must not have demonstrated progressive disease; AND Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues; AND The treatment must be in combination with dexamethasone. 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	Compliance with Authority Required procedures
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		<p>between involved free light chain and uninvolved free light chain; or</p> <p>(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</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(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</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	
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**(b)** *insert in numerical order after existing text:*

	C10427	<p>Multiple myeloma</p> <p>Continuing treatment until progression in patients initiated on dual combination therapy (lenalidomide and dexamethasone), or, in patients initiated on triple therapy (lenalidomide, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond</p> <p>Patient must have previously been authorised with a PBS prescription with this drug for the condition; AND</p> <p>Patient must not have demonstrated progressive disease; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues; AND</p> <p>The treatment must be in combination with dexamethasone.</p> <p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(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</p> <p>(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</p> <p>(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</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(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</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	Compliance with Authority Required procedures
	C10428	<p>Multiple myeloma</p> <p>Initial treatment with triple therapy (lenalidomide, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle</p> <p>The condition must be newly diagnosed; AND</p> <p>The condition must be confirmed by a histological diagnosis; AND</p> <p>Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues; AND</p> <p>The treatment must be in combination with bortezomib and dexamethasone; AND</p>	Compliance with Written Authority Required procedures

		<p>Patient must not have been treated with lenalidomide or bortezomib for this condition; AND The treatment must not exceed a total of 4 cycles under this restriction. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and nomination of which disease activity parameters will be used to assess response. To enable confirmation of eligibility for treatment, current pathology results of (for items a, b, c, g), or, a statement that diagnosis was based on (for items d, e, f) at least one of the following must be provided: (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 will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients and kept on the patient's records. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. 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 declared to be held on the patient's medical records. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	
	C10429	<p>Multiple myeloma Continuing treatment of triple therapy (lenalidomide, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles) Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4; AND Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues; AND The treatment must be in combination with bortezomib and dexamethasone; AND The treatment must not exceed a total of 2 cycles under this restriction. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	Compliance with Authority Required procedures
	C10452	<p>Multiple myeloma Continuing treatment of triple therapy (lenalidomide, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles) Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4; AND Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues; AND The treatment must be in combination with bortezomib and dexamethasone; AND The treatment must not exceed a total of 4 cycles under this restriction. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	Compliance with Authority Required procedures

	C10453	<p>Multiple myeloma Initial treatment with triple therapy (lenalidomide, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle The condition must be newly diagnosed; AND The condition must be confirmed by a histological diagnosis; AND Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues; AND The treatment must be in combination with bortezomib and dexamethasone; AND Patient must not have been treated with lenalidomide or bortezomib for this condition; AND The treatment must not exceed a total of 4 cycles under this restriction. The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, and nomination of which disease activity parameters will be used to assess response. To enable confirmation of eligibility for treatment, current pathology results of (for items a, b, c, g), or, a statement that diagnosis was based on (for items d, e, f) at least one of the following must be provided: (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 will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients and kept on the patient's records. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. 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 declared to be held on the patient's medical records. Patients receiving this drug under the PBS listing must be registered in the i-access risk management program.</p>	Compliance with Written Authority Required procedures
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**[6] Schedule 3, entry for Mepolizumab**

*insert in numerical order after existing text:*

	C10483	<p>P10483 Uncontrolled severe eosinophilic asthma Grandfather treatment - use in a patient initiated with non-PBS subsidised pre-filled syringe or pen device Patient must have received non-PBS-subsidised treatment with this biological medicine's pre-filled syringe or pen device for this PBS-indication prior to 1 June 2020; AND Patient must have demonstrated or sustained an adequate response to treatment with this biological medicine if the patient has received at least the week 28 dose of this biological medicine; AND Patient must be receiving treatment with this drug for this condition at the time of application; AND Patient must be under the care of the same physician for at least 6 months; OR Patient must have been diagnosed with severe asthma by a multidisciplinary severe asthma clinic team; AND Patient must have had, prior to commencement of this drug, a diagnosis of asthma confirmed and</p>	Compliance with Written Authority Required procedures
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		<p>documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) Forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR</p> <p>Patient must have had, prior to commencement of this drug, a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma; AND</p> <p>Patient must have had a blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of a biological medicine treatment for severe asthma; OR</p> <p>Patient must have had a blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids prior to commencement of a biological medicine treatment for severe asthma; AND</p> <p>Patient must have had a duration of asthma of at least 1 year prior to commencement of this biological medicine; AND</p> <p>Patient must have failed to achieve adequate control with optimised asthma therapy prior to commencement of this biological medicine despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND</p> <p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.</p> <p>Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.</p> <p>Patient must be aged 12 years or older.</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND</p> <p>(ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the 12 months prior to commencing treatment with a biological medicine for severe asthma, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application (if not already provided).</p> <p>The following initiation criteria indicate failure to achieve adequate control with optimised asthma therapy and must be declared to have been met at the time of the application:</p> <p>(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0 prior to commencement with a biological medicine for severe asthma; AND</p> <p>(b) while receiving optimised asthma therapy in the 12 months prior to commencing treatment with a biological medicine for severe asthma, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.</p> <p>An Asthma Control Questionnaire (5 item version) assessment and/or an assessment of a reduction in the patient's maintenance oral corticosteroid dose to determine whether the patient has achieved or sustained an adequate response to non-PBS-subsidised treatment, must be conducted immediately (no later than 4</p>	
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		<p>weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been 28 weeks or greater.</p> <p>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 the same treatment cycle.</p> <p>A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 3 biological medicines within the same treatment cycle.</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>A respiratory physician; and</p> <p>A pharmacist, nurse or asthma educator.</p> <p>An adequate response to this biological medicine is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR</p> <p>(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form which seeks details of the following (if not already provided):</p> <p>(i) prior optimised asthma drug therapy (date of commencement and duration of therapy); and</p> <p>(ii) eosinophil pathology report (eosinophil counts and dates); and</p> <p>(iii) ACQ-5 scores including the date of assessment of the patient's symptoms, or details of the maintenance oral corticosteroid dose.</p>	
	C10484	<p>P10484</p> <p>Uncontrolled severe eosinophilic asthma</p> <p>Grandfather treatment - use in a patient initiated with non-PBS-subsidised pre-filled syringe or pen device</p> <p>Patient must have received non-PBS-subsidised treatment with this biological medicine's pre-filled syringe or pen device for this PBS-indication prior to 1 June 2020; AND</p> <p>Patient must have demonstrated or sustained an adequate response to treatment with this biological medicine if the patient has received at least the week 28 dose of this biological medicine; AND</p> <p>Patient must be receiving treatment with this drug for this condition at the time of application; AND</p> <p>Patient must be under the care of the same physician for at least 6 months; OR</p> <p>Patient must have been diagnosed with severe asthma by a multidisciplinary severe asthma clinic team; AND</p> <p>Patient must have had, prior to commencement of this drug, a diagnosis of asthma confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by the following standard clinical features: (i) Forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), or (ii) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, or (iii) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak</p>	Compliance with Written Authority Required procedures



		<p>expiratory flow rates during 14 days; OR  Patient must have had, prior to commencement of this drug, a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma; AND  Patient must have had a blood eosinophil count greater than or equal to 300 cells per microlitre prior to commencement of a biological medicine treatment for severe asthma; OR  Patient must have had a blood eosinophil count greater than or equal to 150 cells per microlitre while receiving treatment with oral corticosteroids prior to commencement of a biological medicine treatment for severe asthma; AND  Patient must have had a duration of asthma of at least 1 year prior to commencement of this biological medicine; AND  Patient must have failed to achieve adequate control with optimised asthma therapy prior to commencement of this biological medicine despite formal assessment of and adherence to correct inhaler technique, which has been documented; AND  The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.  Must be treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma.  Patient must be aged 12 years or older.  Optimised asthma therapy includes:  (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;  AND  (ii) treatment with oral corticosteroids, either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the 12 months prior to commencing treatment with a biological medicine for severe asthma, unless contraindicated or not tolerated.  If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application (if not already provided).  The following initiation criteria indicate failure to achieve adequate control with optimised asthma therapy and must be declared to have been met at the time of the application:  (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0 prior to commencement with a biological medicine for severe asthma; AND  (b) while receiving optimised asthma therapy in the 12 months prior to commencing treatment with a biological medicine for severe asthma, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.  An Asthma Control Questionnaire (5 item version) assessment and/or an assessment of a reduction in the patient's maintenance oral corticosteroid dose to determine whether the patient has achieved or sustained an adequate response to non-PBS-subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been 28 weeks or greater.  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 the same treatment cycle.  A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 3 biological medicines within the same treatment cycle.</p>	
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		<p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>A respiratory physician; and</p> <p>A pharmacist, nurse or asthma educator.</p> <p>An adequate response to this biological medicine is defined as:</p> <p>(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,</p> <p>OR</p> <p>(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.</p> <p>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.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Severe Eosinophilic Asthma Grandfather PBS Authority Application - Supporting Information Form which seeks details of the following (if not already provided):</p> <p>(i) prior optimised asthma drug therapy (date of commencement and duration of therapy); and</p> <p>(ii) eosinophil pathology report (eosinophil counts and dates); and</p> <p>(iii) ACQ-5 scores including the date of assessment of the patient's symptoms, or details of the maintenance oral corticosteroid dose.</p>	
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## [7] Schedule 5

*omit table and substitute:*

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

Listed drug	Form	Manner of administration
Abatacept	Powder for I.V. infusion 250 mg	Injection
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Injection
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	Injection
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	Injection
Ambrisentan	Tablet 5 mg	Oral
Ambrisentan	Tablet 10 mg	Oral
Benralizumab	Injection 30 mg in 1 mL single dose pre-filled syringe	Injection
Benralizumab	Injection 30 mg in 1 mL single dose pre-filled pen	Injection
Bosentan	Tablet 62.5 mg (as monohydrate)	Oral

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Bosentan	Tablet 125 mg (as monohydrate)	Oral
Dornase alfa	Solution for inhalation 2.5 mg (2,500 units) in 2.5 mL	Inhalation
Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium)	Injection
Epoprostenol	Powder for I.V. infusion 500 micrograms (as sodium) with 2 vials diluent 50 mL	Injection
Epoprostenol	Powder for I.V. infusion 1.5 mg (as sodium)	Injection
Epoprostenol	Powder for I.V. infusion 1.5 mg (as sodium) with 2 vials diluent 50 mL	Injection
Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection
Etanercept	Injection 50 mg in 1 mL single use auto-injector, 4	Injection
Etanercept	Injections 50 mg in 1 mL single use pre-filled syringes, 4	Injection
Iloprost	Solution for inhalation 20 micrograms (as trometamol) in 2 mL	Inhalation
Infliximab	Powder for I.V. infusion 100 mg	Injection
Ivacaftor	Sachet containing granules 50 mg	Oral
Ivacaftor	Sachet containing granules 75 mg	Oral
Ivacaftor	Tablet 150 mg	Oral
Lenalidomide	Capsule 5 mg	Oral
Lenalidomide	Capsule 10 mg	Oral
Lenalidomide	Capsule 15 mg	Oral
Lenalidomide	Capsule 25 mg	Oral
Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 100 mg and ivacaftor 125 mg	Oral
Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 150 mg and ivacaftor 188 mg	Oral
Lumacaftor with ivacaftor	Tablet containing lumacaftor 100 mg with ivacaftor 125 mg	Oral

Lumacaftor with ivacaftor	Tablet containing lumacaftor 200 mg with ivacaftor 125 mg	Oral
Macitentan	Tablet 10 mg	Oral
Mannitol	Pack containing 280 capsules containing powder for inhalation 40 mg and 2 inhalers	Inhalation by mouth
Mepolizumab	Powder for injection 100 mg	Injection
Mepolizumab	Injection 100 mg in 1 mL single dose pre-filled pen	Injection
Omalizumab	Injection 75 mg in 0.5 mL single dose pre-filled syringe	Injection
Omalizumab	Injection 150 mg in 1 mL single dose pre-filled syringe	Injection
Pomalidomide	Capsule 3 mg	Oral
Pomalidomide	Capsule 4 mg	Oral
Riociguat	Tablet 500 micrograms	Oral
Riociguat	Tablet 1 mg	Oral
Riociguat	Tablet 1.5 mg	Oral
Riociguat	Tablet 2 mg	Oral
Riociguat	Tablet 2.5 mg	Oral
Rituximab	Solution for I.V. infusion 500 mg in 50 mL	Injection
Sildenafil	Tablet 20 mg (as citrate)	Oral
Tadalafil	Tablet 20 mg	Oral
Tezacaftor with ivacaftor and ivacaftor	Pack containing 28 tablets tezacaftor 100 mg with ivacaftor 150 mg and 28 tablets ivacaftor 150 mg	Oral
Tocilizumab	Concentrate for injection 80 mg in 4 mL	Injection
Tocilizumab	Concentrate for injection 200 mg in 10 mL	Injection
Tocilizumab	Concentrate for injection 400 mg in 20 mL	Injection
Ustekinumab	Solution for I.V. infusion 130 mg in 26 mL	Injection
Vedolizumab	Powder for injection 300 mg	Injection